

PATENT ABSTRACTS OF JAPAN

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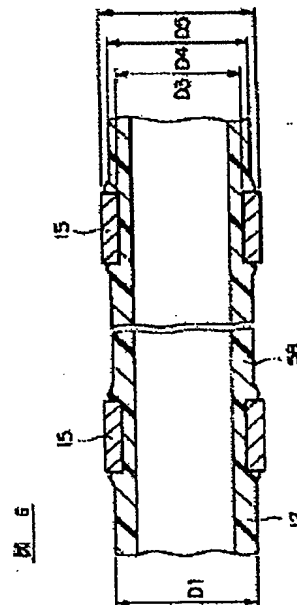
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(54) MEDICAL TOOL AND METHOD FOR MANUFACTURING THE SAME

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a medical tool that helps minimize the outside diameter of a tube portion to which a metal ring is attached and can be easily inserted into a celom, and a method for manufacturing the medical tool that can very easily manufacture the medical tool without causing a defect to the tube portion.

SOLUTION: After forcibly reducing the outside diameter of a synthetic resin tube 12 of a prescribed length range including a position in which the metal ring 15 is mounted and forming a reduced diameter portion 58 having an outside diameter equal to or smaller than the inside diameter of the metal ring 15, by mounting the metal ring 15 to the reduced diameter portion 58 and heating, the outside diameter of the reduced diameter portion 58 is restored, and the metal ring 15 is fixed to a prescribed position of the tube 12.



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CLAIMS

[Claim(s)]

[Claim 1]The diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring is made to reduce compulsorily, A medical device restoring an outer diameter of said diameter reduction part, and having fixed said metal ring to a prescribed position of said tube by equipping said diameter reduction part with a metal ring after forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, and heating after that.

[Claim 2]The medical device according to claim 1, wherein ratios of an outer diameter of said tube after restoration to an outer diameter of said metal ring are 0.7-1.

[Claim 3]The medical device according to claim 1 or 2, wherein ratios of an outer diameter of said tube after restoration to an inside diameter of said metal ring are 1-1.2.

[Claim 4]An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction.

A balloon part which a proximal edge seal part of a balloon part is joined to a distal end of said outer tube, and said lumen for balloon extension and an inside open for free passage.

A distal end seal part of a balloon part is joined to a distal end of an inner tube so that space for extension sealed inside said balloon part may be formed, At least one imaging ring with which a peripheral part of an inner tube which extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, and said inner tube located in an inside of said balloon part was equipped.

Are the balloon catheter provided with the above and the diameter of an outer diameter of an inner tube of a predetermined length range including a position equipped with said imaging ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, by equipping said diameter reduction part with an imaging ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said imaging ring is fixed to a prescribed position of said inner tube.

[Claim 5]The balloon catheter according to claim 4, wherein ratios of an outer diameter of said inner tube after restoration to an outer diameter of said imaging ring are 0.7-1.

[Claim 6]The balloon catheter according to claim 4 or 5, wherein ratios of an outer diameter of said inner tube after restoration to an inside diameter of said imaging ring are 1-1.2.

[Claim 7]The diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring is made to reduce compulsorily, A manufacturing method of a medical device restoring an outer diameter of said diameter reduction part, and fixing said metal ring to a prescribed position of said tube by equipping said diameter reduction part with a metal ring after forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, and heating after that.

[Claim 8]A manufacturing method of the medical device according to claim 7, wherein the cooking temperature of said diameter reduction part is about 5-20 ** in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said tube.

[Claim 9]A manufacturing method of the medical device according to claim 7 or 8, wherein said diameter reduction part is formed by pulling a distal end of said tube to shaft orientations.

[Claim 10]A manufacturing method of the medical device according to any one of claims 7 to 9 characterized by forming said diameter reduction part where a mandrel is inserted in an inside of a lumen of said tube.

[Claim 11]An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal edge seal part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, An inner tube which a distal end seal part of a balloon part

JP,2002-291900,A [CLAIMS]

is joined to a distal end of an inner tube, and extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, At least one imaging ring with which a peripheral part of said inner tube located in an inside of said balloon part was equipped, It is a manufacturing method of a balloon catheter which ****, the diameter of an outer diameter of an inner tube of a predetermined length range including a position equipped with said imaging ring is made to reduce compulsorily, and after forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, said diameter reduction part is equipped with at least one imaging ring.

Then, a manufacturing method of a balloon catheter restoring an outer diameter of said diameter reduction part, and fixing said imaging ring to a prescribed position of said inner tube by heating.

[Claim 12]A manufacturing method of the balloon catheter according to claim 11, wherein the cooking temperature of said diameter reduction part is about 5-20 ** in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said inner tube.

[Claim 13]A manufacturing method of the balloon catheter according to claim 11 or 12, wherein said diameter reduction part is formed by pulling a distal end of said inner tube to shaft orientations.

[Claim 14]A manufacturing method of the balloon catheter according to any one of claims 11 to 13 characterized by forming said diameter reduction part where a mandrel is inserted in an inside of a lumen of said inner tube.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to medical devices, such as a balloon catheter, and the manufacturing method of those, and relates to the medical device in which the imaging ring for the medical device in which the metal ring used as an electrode, a sensor, etc. is attached in more detail, or X ray imaging is attached, and its manufacturing method.

[0002]

[Description of the Prior Art]In recent years, the iatrotechnique tends to go to a low invasion therapy. For example, instead of a former coronary-bypass operation, a measure is being taken more often with the balloon catheter for vasodilatation by strangulation of coronary arteries. This therapeutic method has expanded the scope increasingly, in order to ease a patient's burden greatly with an economical advantage. The structure of the balloon catheter used for strangulation extension of still more efficient and easy coronary arteries with it is searched for.

[0003]As what is called a PTCA balloon catheter for inserting into a blood vessel, extending a narrow segment by swelling a balloon part, and aiming at an improvement of the blood flow by the side of a narrow segment tip, in order to treat an intravascular narrow segment, There are a balloon catheter of an excess the wire method and a balloon catheter (for example, JP,2000-217923,A) of a monorail method. In the balloon catheter of these methods, a guidewire is previously passed to an intravascular narrow segment, then, each sends in a balloon catheter to a narrow segment along with this guidewire, and a narrow segment is extended by swelling a balloon part.

[0004]The inside of the outer tube which constitutes a catheter tube in the conventional balloon catheter has many by which an inner tube is arranged, using such a PTCA balloon catheter as the start. It was used as a guidewire insertion hole, thermal melting arrival of the distal end of a balloon part was carried out to the periphery of the distal end of an inner tube, and the lumen of an inner tube has sealed the inside of a balloon part.

[0005]In the conventional balloon catheter, in order to grasp the position of the PTCA balloon catheter inserted into the blood vessel, the imaging ring which comprised tungsten etc. is attached to the periphery of the inner tube located in the inside of a balloon part. Generally, since an imaging ring is inserted in from the outside of an inner tube, the outer diameter of the portion becomes larger than the outer diameter of an inner tube, and the shape of an inner tube becomes a convex extremely. For this reason, when it is going to pass the balloon catheter in the state where the balloon part was folded up, to the strangulation portion of a blood vessel, it is possible to become an obstacle.

[0006]As shown in JP,H8-289934,A, a concave is provided in the prescribed position of an inner tube by processing means, such as etching, and the structure which attached the imaging ring to the concave is proposed. However, in the balloon catheter of this structure, when forming a concave in the periphery of the inner tube of thin meat extremely, the thickness of an inner tube changes too much thinly, and it is easy to produce a defect in an inner tube. After processing a concave into an inner tube, it is difficult to attach an imaging ring to the concave.

[0007]In medical devices other than a balloon catheter, there is a medical device in which the metal ring used as an electrode, a sensor, etc. in addition to the use of an imaging ring etc. is attached to the periphery of the tube made of a synthetic resin, and it has the same inconvenience as a balloon catheter also in this case.

[0008]

[Problem(s) to be Solved by the Invention]In view of such the actual condition, accomplish this invention, and the purpose of this invention, It is providing the manufacturing method of the medical device which could make small the outer diameter of the tube portion to which a metal ring is attached as much as possible, and was

excellent in the insertion nature into the abdominal cavity, and the medical device for which the medical device can be manufactured very easily without making a tube produce a defect.

[0009]The 2nd purpose of this invention also receives the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially, The balloon catheter which can insert the distal end of a balloon catheter easily and was excellent in the insertion characteristic, It is providing the manufacturing method of the balloon catheter which can be manufactured very easily, without making an inner tube produce a defect for the balloon catheter.

[0010]

[Means for Solving the Problem]In order to attain the 1st purpose of the above, a medical device concerning this invention, The diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, by equipping said diameter reduction part with a metal ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said metal ring is fixed to a prescribed position of said tube.

[0011]Preferably, ratios of an outer diameter of said tube after restoration to an outer diameter of said metal ring are 0.7-1.

[0012]Preferably, ratios of an outer diameter of said tube after restoration to an inside diameter of said metal ring are 1-1.2.

[0013]A manufacturing method of a medical device concerning this invention makes the diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring reduce compulsorily, After forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, by equipping said diameter reduction part with a metal ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said metal ring is fixed to a prescribed position of said tube.

[0014]Preferably, the cooking temperature of said diameter reduction part is about 5-20 ** in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said tube.

[0015]Preferably, said diameter reduction part is formed by pulling a distal end of said tube to shaft orientations.

[0016]Preferably, it is in a state where a mandrel was inserted in an inside of a lumen of said tube, and said diameter reduction part is formed.

[0017]In order to attain the 2nd purpose of the above, a balloon catheter concerning this invention, An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal edge seal part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, An inner tube which a distal end seal part of a balloon part is joined to a distal end of an inner tube, and extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, At least one imaging ring with which a peripheral part of said inner tube located in an inside of said balloon part was equipped, Are a balloon catheter which **** and the diameter of an outer diameter of an inner tube of a predetermined length range including a position equipped with said imaging ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, by equipping said diameter reduction part with an imaging ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said imaging ring is fixed to a prescribed position of said inner tube.

[0018]Preferably, ratios of an outer diameter of said inner tube after restoration to an outer diameter of said imaging ring are 0.7-1.

[0019]Preferably, ratios of an outer diameter of said inner tube after restoration to an inside diameter of said imaging ring are 1-1.2.

[0020]A manufacturing method of a balloon catheter concerning this invention, An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal edge seal part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, An inner tube which a distal end seal part of a balloon part is joined to a distal end of an inner tube, and extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, At least one imaging ring with which a peripheral part of said inner tube located in an inside of said balloon part was equipped, The diameter of an outer diameter of an inner tube of a predetermined length range which is a manufacturing method of a balloon catheter which **** and includes a position equipped with said imaging ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, by equipping said diameter reduction part with at least one imaging

ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said imaging ring is fixed to a prescribed position of said inner tube.

[0021] Preferably, the cooking temperature of said diameter reduction part is about 5-20 °C in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said inner tube.

[0022] Preferably, said diameter reduction part is formed by pulling a distal end of said inner tube to shaft orientations.

[0023] Preferably, it is in a state where a mandrel was inserted in an inside of a lumen of said inner tube, and said diameter reduction part is formed.

[0024]

[Function] Since the diameter reduction part which makes the diameter of the outer diameter of the synthetic resin tube of the predetermined length range which includes the position equipped with a metal ring in the manufacturing method of the medical device concerning this invention reduce compulsorily, and has an inside diameter of a metal ring and an outer diameter below equivalent is formed, the work which equips the diameter reduction part of a tube with a metal ring is easy. The outer diameter of said diameter reduction part is restored to near the original outer diameter by equipping the diameter reduction part with a metal ring, and heating after that. Therefore, a metal ring serves as structure embedded on the periphery of an inner tube, and is fixed to the prescribed position.

[0025] Thus, the manufactured medical device serves as the structure where a metal ring is embedded on the periphery of an inner tube, and it is lost in the fixing point of the metal ring that a metal ring projects of it too much from the periphery of a tube. As a result, it becomes possible to make small the outer diameter of the portion equipped with a metal ring, and the insertion characteristic of a medical device improves.

[0026] The medical device concerning this invention can be easily manufactured in comparison, and the manufacturing method of the medical device concerning this invention is enough also as the bonding strength of a metal ring and a tube, and, moreover, it is hard to produce defects, like a tube becomes thin meat to a degree very much etc. in it on the occasion of the manufacture. On the occasion of junction in a metal ring and a tube, adhesives etc. are not necessarily needed.

[0027] In the manufacturing method of the balloon catheter concerning this invention. Since the diameter reduction part which makes the diameter of the outer diameter of the inner tube of the predetermined length range including the position equipped with an imaging ring reduce compulsorily, and has an inside diameter of said imaging ring and an outer diameter below equivalent is formed, the work which equips the diameter reduction part of an inner tube with an imaging ring is easy. The outer diameter of said diameter reduction part is restored to near the original outer diameter by equipping the diameter reduction part with an imaging ring, and heating after that. Therefore, an imaging ring serves as structure embedded on the periphery of an inner tube, and is fixed to the prescribed position.

[0028] Thus, the manufactured balloon catheter serves as the structure where an imaging ring is embedded on the periphery of an inner tube, and it is lost in the fixing point of the imaging ring that an imaging ring projects of it too much from the periphery of an inner tube. As a result, it is in the state which folded up the balloon part on the periphery of the inner tube, and it is possible to become possible to make the outer diameter small, and to insert the distal end of a balloon catheter easily also to the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of a balloon catheter improves.

[0029] The balloon catheter concerning this invention can be easily manufactured in comparison, and the manufacturing method of the balloon catheter concerning this invention is enough also as the bonding strength of an imaging ring and an inner tube, and, moreover, it is hard to produce defects, like an inner tube becomes thin meat to a degree very much etc. in it on the occasion of the manufacture. On the occasion of junction to an imaging ring and an inner tube, adhesives etc. are not necessarily needed.

[0030]

[Embodiment of the Invention] Hereafter, this invention is explained based on the embodiment shown in Drawings. The balloon catheter 2 concerning this embodiment shown in drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this embodiment is used for PTCA.

[0031] The balloon catheter 2 for extension of this embodiment is the so-called balloon catheter of a monorail method.

It has the balloon part 4, the outer tube 6 as a catheter tube, the inner tube 12, and the connector 8.

[0032]The balloon part 4 shown in drawing 1 and drawing 4 has the cylindrical section 4a which has a bigger outer diameter than the outer diameter of the outer tube 6 in the state where it swelled. The tapered shape reducing parts 4b and 4c which follow the both ends of the cylindrical section 4a at it, and the proximal edge seal part 5 and the distal end seal part 7 which follow them, respectively are fabricated to one. The proximal edge seal part 5 has an outer diameter smaller than the cylindrical section 4a so that it may be connected to the distal end peripheral part of the outer tube 6. The distal end seal part 7 has an outer diameter smaller than the proximal edge seal part 5 so that it may be connected to the distal end peripheral part of the inner tube 12.

[0033]Although the thickness in particular of the balloon part 4 is not limited, it is 30-150 micrometers preferably 15-300 micrometers. As long as the cylindrical section 4a of the balloon part 4 is cylindrical, it may not be limited in particular but a cylinder or the shape of a multiple cartridge may have as it. The outer diameter of the balloon part 4 at the time of extension is determined by factors, such as an inside diameter of a blood vessel, and is usually 3-7 mm preferably about 1.5-10.0 mm. Although the shaft-orientations length of the cylindrical section 4a in this balloon part 4 is determined by factors, such as a size of an intravascular narrow segment, and is not limited in particular, it is 20-40 mm preferably 15-50 mm. The balloon part 4 before extending is folded up around the inner tube 12, and is twisted, and the outer diameter is small as much as possible.

[0034]As for the construction material which constitutes the balloon part 4, it is preferred that it is the construction material which has a certain amount of flexibility, For example, polyethylene, polyethylene terephthalate, polypropylene, The copolymer of ethylene, such as ethylene propylene rubber, and other alpha olefins, An ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), the constructed type ethylene-vinylacetate copolymer of a bridge, Polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and they are polyethylene, polyethylene terephthalate, and polyamide preferably. By introducing a fluid into an inside, the balloon part 4 comprises construction material and thickness more flexible than the tubes 6 and 12 so that it can swell or fade.

[0035]the 1st joining section 5a joined by the proximal edge seal part 5 of the balloon part 4 overlapping with the distal end of the outer tube 6 as shown in drawing 4, and this 1st joining section 5a — abbreviated — it has a part for the 1st non-connecting part 5b that does not overlap with the distal end of the outer tube 6 with the same outer diameter. having joined the 1st joining section 5a to the distal end periphery of the outer tube 6 by thermal melting arrival, adhesion, or other means — the outer tube 6 — 10 [lumen / 1st] is open for free passage with the space for internal extension of the balloon part 4. The distal end seal part 7 of the balloon part 4 is joined by thermal melting arrival, adhesion, or other means to the distal end periphery of the inner tube 14, and the space for internal extension of the balloon part 4 is sealed to the exterior except 1st lumen 10. It is a passage for [of the outer tube 6] 10 sending the 1st lumen of a fluid into the internal growth space of the balloon part 4, and making the balloon part 4 extend, or sampling a fluid from the growth space of the balloon part 4, and shrinking the balloon part 4.

[0036]According to this embodiment, in the proximal edge seal part 5 of the balloon part 4, the ratio (La:Lb) of shaft-orientations length La of the 1st joining section 5a and the shaft-orientations length Lb for the 1st non-connecting part 5b is in the range of 1:2-1:5 preferably in 1:1-1:10, and a pan. Shaft-orientations length La of the 1st joining section 5a is 2-5 mm preferably. The shaft-orientations length Lb for the 1st non-connecting part 5b is 15-20 mm preferably. It is in the tendency for junction to become insufficient if shaft-orientations length La of the 1st joining section 5a is too short, and when too long, the length of areas of overlap becomes long and it is in the tendency for the pliability in the portion to fall. It is in the tendency to have the same inconvenience as the conventional balloon catheter when the shaft-orientations length Lb for the 1st non-connecting part 5b is too short, and when too long, it is in the tendency for the intensity of the balloon part 4 to fall. The overall length Lc of the proximal edge seal part 5 is 17-25 mm preferably.

[0037]As shown in drawing 4, as for the growth space [of the balloon part 4], and distal end side of the outer tube 6, the 1st lumen of the inner tube 12 is extended to shaft orientations in the shape of the same axle in the inside of 10, and has the so-called catheter tube structure of coaxial structure. The periphery of the inner tube 12 located in the inside of the balloon part 4 is equipped with the imaging ring 15 of the couple, and when inserting the balloon catheter 2 in the living body, imaging is possible about the position of the imaging ring 15 through a living body's exterior to X-rays etc. Metal, such as gold, platinum, and tungsten, is illustrated as construction material of the imaging ring 15.

[0038]The shaft-orientations length Lr of each imaging ring 15 is 1-1.2 mm still more preferably 0.5-2 mm preferably. The distal end of the imaging ring 15 arranged at the distal end side of the balloon catheter 2 is located in the position corresponding to intersection 4ac of the cylindrical section 4a and the tapered shape reducing part 4c in the balloon part 4. The proximal edge of the imaging ring 15 arranged at the proximal edge side of the balloon catheter 2 is located in the position corresponding to intersection 4ab of the cylindrical

section 4a and the tapered shape reducing part 4b in the balloon part 4.

[0039] That is, the distance L_s from the distal end of the imaging ring 15 by the side of a distal end to the proximal edge of the imaging ring 15 by the side of a proximal edge corresponds to the length of the cylindrical section 4a. Therefore, the position of the cylindrical section 4a in the balloon part 4 can be correctly grasped by detecting the position of the imaging ring 15 of a couple through X-rays etc. This cylindrical section 4a is a portion which contributes to extension of the narrow segment produced in the blood vessel etc. These imaging rings 15 are being embedded and fixed to the periphery of the inner tube 12 as shown in drawing 6. The embedding fixing method is mentioned later.

[0040] As shown in drawing 5, the tip taper part 7a to which an outer diameter becomes thin towards the distal end periphery of the inner tube 12 is formed in the tip part of the distal end seal part 7 of the balloon part 4. The distal end of the inner tube 12 has projected to the pan of the tip taper part 7a in shaft orientations at the distal end side.

As a result, a part for the 2nd non-connecting part 12b that is not joined to the 2nd joined part 12a to which the distal end seal part 7 of the balloon part 4 is joined is formed in the distal end periphery of the inner tube 12.

[0041] According to this embodiment, in the distal end seal part 7 of the balloon part 4, the ratio ($L_d:L_e$) of the shaft-orientations length L_d of the 2nd joining section 12a and the shaft-orientations length L_e for the 2nd non-connecting part 12b is in the range of 1.5:1-3:1 preferably in 1:2-4:1, and a pan. The shaft-orientations length L_d of the 2nd joining section 12a is 1.5-3 mm preferably. The shaft-orientations length L_e for the 2nd non-connecting part 12b is 0.5-1.5 mm preferably. It is in the tendency for junction to become insufficient if the shaft-orientations length L_d of the 2nd joining section 12a is too short, and when too long, the length of a joining section becomes long and it is in the tendency for the pliability in the portion to fall. It is in the tendency to have the same inconvenience as the conventional balloon catheter when the shaft-orientations length L_e for the 2nd non-connecting part 12b is too short, and when too long, it is the futility of material, and it is in the tendency which becomes the obstacle of a therapy. The 2nd joining section 12a and the total length L_f for the 2nd non-connecting part 12b are 3.5-5.5 mm preferably. In this embodiment, the taper part 12c which also becomes a distal end periphery of the inner tube 12 with a taper is formed.

[0042] 14 [lumen / 2nd] is formed in the inside of the inner tube 12, and the opening of the distal end opening 20 is carried out to it by the distal end side rather than the distal end seal part 7 of the balloon part 4. As shown in drawing 1 and drawing 2, the proximal edge opening 22 of the inner tube 12 penetrates the breakthrough 21 of a tube wall located in the middle of the longitudinal direction of the outer tube 6, and is carrying out the opening outside. The periphery of the proximal edge opening 22 of the inner tube 12 and the periphery of the breakthrough 21 of the tube wall of the outer tube 6 are airtightly joined by the thermal melting arrival method. Although the shape in particular of the proximal edge opening 22 of the inner tube 12 is not limited but can take various shape, such as circular and an ellipse form, it is elliptical [which cut the open end of the inner tube 12 aslant] in this embodiment. The 2nd lumen turns into a lumen for guidewire insertion which the guidewire 42 shown in drawing 4 for 14 to guide [of the inner tube 12] the balloon catheter 2 into the abdominal cavity inserts in. The guidewire 42 is 0.25-0.6 mm still more preferably 0.1-1 mm preferably, although it constitutes, for example from single track or stranded wires, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, and the outer diameter in particular is not limited.

[0043] In this embodiment, the outer tube 6 The 1st outer tube member 6a of a circular section, It has the 2nd outer tube member 6b of the irregular shape cross joined to the proximal end part of the 1st outer tube member 6a concerned, and the proximal edge opening 22 of the inner tube 12 penetrates the tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and is carrying out the opening outside. Although the shaft-orientations length L_2 in particular of the 1st outer tube 6a is not limited, it is 200-300 mm still more preferably 100-400 mm preferably.

[0044] Although the 1st outer tube member 6a may comprise the same construction material as the balloon part 4, for example, It is preferred to comprise construction material which has flexibility, and For example, polyethylene, Polyethylene terephthalate, polypropylene, ethylene propylene rubber, An ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), the constructed type ethylene-vinylacetate copolymer of a bridge, Polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and it comprises polyethylene, polyamide, and polyimide preferably.

[0045] As an elastic synthetic resin which constitutes the 1st outer tube member 6a, that whose JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, is about 50A-90A preferably can be used.

[0046] Although the inner tube 12 can be constituted from soft synthetic resin of the same construction material as the 1st outer tube 6a, a hard synthetic resin may constitute it from the 1st outer tube 6a. As for the position, as for, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the 1st outer

tube member 6a, it is preferred that it is a position of the distal end of the 1st outer tube member 6a to the length L1, and the length L1 is 200–300 mm still more preferably 150–350 mm preferably. Although the outer diameter in particular of the 1st outer tube member 6a is not limited, it is 0.5–1 mm still more preferably 0.5–5 mm preferably. Although the thickness in particular of the 1st outer tube member 6a is not limited, it is 0.1–0.2 mm still more preferably 0.05–0.5 mm preferably.

[0047]Although the outer diameter of the inner tube 12 is determined that a crevice is formed and is not limited in particular between the 1st outer tube members 6a, it is 0.3–0.8 mm still more preferably 0.3–3 mm preferably. Especially if the inside diameter of the inner tube 12 is a path which can insert in the guidewire 42, it will not be limited, for example, it is 0.25–0.6 mm preferably 0.15–1.0 mm.

[0048]Although the 2nd outer tube member 6b may be constituted from same construction material as the 1st outer tube member 6a, constituting from other construction material is preferred. For example, it is preferred to constitute the 1st outer tube member 6a from the 2nd outer tube member 6b with an elastic synthetic resin.

[0049]As an elastic synthetic resin which constitutes the 1st outer tube member 6a, That whose JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, is about 50A–90A preferably can be used, As a hard synthetic resin which constitutes the 2nd outer tube member 6b, JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, can use the thing of 50D–75D.

[0050]As shown in drawing 2 (B), in this embodiment the cross section contour shape of the 2nd outer tube member 6b, The maximum sectional width x_m of the catheter tube of an X axial direction vertical to a Y-axis in the section of the outer tube member 6b which has elliptical [long and slender] in Y shaft orientations, a ratio (x_m/y_m) with the maximum sectional width y_m of Y shaft orientations is in the range of 0.8–0.1 — the 3rd of section semicircular shapes — lumen 24 and a round cross section — the 4th lumen, along said Y shaft orientations, 26 dissociates and is formed.

[0051]The 3rd lumen, the cross sectional area of the semicircular shapes of 24 should just be cross sectional area sufficient in order that the pressure fluid for balloon extension may circulate, and although it is not limited in particular, it is 0.08–0.20– mm^2 preferably. The 4th lumen, the circular cross sectional area of 26 should just be area sufficient since the reinforcing rod 28 is inserted in an inside, and although it is not limited in particular, it is 0.1–0.2– mm^2 preferably [it is desirable and] to 0.05–0.5– mm^2 and a pan.

[0052]As for the maximum sectional width y_m of Y shaft orientations, in this embodiment, about 0.6–1.2 mm is preferred in the section of the 2nd outer tube member 6b. Since the distal end of the 2nd outer tube member 6b is joined to the proximal edge of the 1st outer tube member 6a of a round cross section, the lateral cross sectional shape of the joined part 9 neighborhood, In order to make it in agreement with circular section shape with the 1st outer tube member 6a, it is considered as sectional shape which changes from an irregular shape cross to a circular section gradually towards the joined part 9.

[0053]the 3rd formed along with the longitudinal direction of this 2nd outer tube member 6b — lumen 24 — the 1st outer tube member 6a — the 1st lumen is open for free passage with 10, it lets these pass, and a fluid is taken in and out of the space for extension of the balloon part 4. It is a lumen for 26 to insert [of the 2nd outer tube 6b] the 4th lumen of the reinforcing rod 28.

the 1st outer tube member 6a — although 10 [lumen / 1st] is open for free passage, the proximal edge of this lumen 26 is closed in the portion of the connector 8, and receipts and payments of a fluid are not performed. The proximal end part of the 2nd outer tube member 6b is connected with the connector 8, and the port of the 2nd outer tube 6b which is open for free passage to 24 the 3rd lumen is formed in it. The port is a portion which goes a pressure fluid in and out.

The 4th lumen is open for free passage to 26.

[0054]The reinforcing rod 28 shown in drawing 1, drawing 2 (A) – drawing 2 (C), and drawing 3, the 2nd outer tube member 6b — the overall length was covered and it was inserted in the inside of 26, and the distal end overcame the joined part 9 with the 1st outer tube member 6a, and the 4th lumen is sticking out of it in 1st lumen 10 of the 1st outer tube member 6a. The proximal end part of the reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

The distal end 28a of the section plate-like reinforcing rod 28, As shown in drawing 1 and drawing 4, it extends to the position which also overcame slightly (preferably L about 3= 1–10 cm) the proximal edge opening 22 of the inner tube 12, and the distal end 2a is not being fixed to the wall of the 1st outer tube member 6a.

[0055]this embodiment — the proximal end part of the reinforcing rod 28 — the 2nd outer tube member 6b — it is continued and inserted in an overall length and is being fixed to the inside of 26 by the 4th lumen of the wall

[the 4th lumen of] of 26 with adhesives in the range of the predetermined length L5 from the proximal edge. namely, -- while the 4th lumen of the reinforcing rod 28 is not being fixed to the wall of 26 by the distal end side at this embodiment from the position of the tube joined part 9 to the predetermined length L4 -- the 1st outer tube member 6a -- it is not being fixed to the wall of 10 by the 1st lumen. Although the predetermined length L4 and L5 in particular is not limited, it is L4=50-150mm preferably. It is L5=1000-15000mm preferably.

[0056]Although the maximum outer diameter of the reinforcing rod 28 is determined possible [the 4th lumen of the insertion to the inside of 26] for the 2nd outer tube member 6b and is not limited in particular, it is 0.3-0.6 mm preferably. The reinforcing rod 28 consists of synthetic resins, such as metallic materials, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, or polyimide, polyamide, and polyethylene terephthalate.

[0057]Especially as a pressure fluid introduced in 1st lumen 10 through the port of the connector 8, although not limited, 50/50 mixed water solution of a radiopacity medium and a physiological saline, etc. are used, for example. It is for using radiation and imaging the position of the balloon part 4 and the outer tube 6 at the time of use of the balloon catheter 2, to include a radiopacity medium. Although the pressure in particular of the pressure fluid for swelling the balloon part 4 is not limited, it is about 4-18 atmospheres preferably 3-12 atmospheres in absolute pressure.

[0058]It is preferred to have covered with this embodiment the covering material which comprises the hydrophilic polymer material which has lubricity in the periphery of the outer tube 6 which comprises the 1st outer tube member 6a and the 2nd outer tube member 6b by a damp or wet condition. By covering the periphery of the outer tube 6 with such covering material, reduction of the insertion resistance at the time of inserting the balloon catheter 2 in a blood vessel etc. can be aimed at. Although the periphery of the balloon 4 may also be covered with covering material, the balloon part 4 extends narrow segments, such as a blood vessel. When extending a narrow segment, it is not necessarily preferred that a balloon part is slippery to a narrow segment.

So, the covering material which comprises hydrophilic polymer material has covered only the periphery of the outer tube 6 in this embodiment.

[0059]As hydrophilic polymer material, there are a thing of a naturally-occurring-polymers system and a thing of a synthetic macromolecule system. As a thing of a naturally-occurring-polymers system, a starch system, a cellulose type, a tannin NIGUNIN system, a polysaccharide system, a protein system, etc. are illustrated. As a thing of a synthetic macromolecule system, a PVA system, a polyethylene oxide system, An acrylic acid series, a maleic anhydride system, a phthalate system, water soluble polyester, ketone aldehyde resin, an acrylamide (meta) system, a vinyl heterocycle system, a polyamine system, a poly electrolyte, a water-soluble nylon system, an acrylic acid glycidyl acrylate system, etc. are illustrated.

[0060]Also in these, as hydrophilic polymer material which can be conveniently used as covering material of the outer tube 6, Especially A cellulose type polymeric material (for example, hydroxypropylcellulose), A polyethylene oxide system polymeric material (for example, polyethylene glycol), A maleic anhydride system polymeric material (for example, a maleic anhydride copolymer like a methyl vinyl ether maleic anhydride copolymer), Since a low coefficient of friction is obtained by being stabilized, an acrylamide system polymeric material (for example, polydimethyl acrylamide), water-soluble nylon (for example, AQ-nylon P-70 by Toray Industries, Inc.), or those derivatives are preferred.

[0061]Next, the manufacturing method of the balloon catheter 2 concerning this embodiment is explained. First, the balloon part 4 shown in drawing 4 is formed. The balloon part 4 may be fabricated by the dipping method which dips the mandrel for balloon membrane shaping into a solution, and fabricates it, and may be fabricated by blow molding.

[0062]Especially as thermoplastics in the solution used for a dipping method, although not limited, VCM/PVC system resin, urethane system resin, amide system resin, olefin system resin, imide system resin, etc. can be illustrated, for example. Also in it, urethane system resin excellent in the bending-fatigue-resistance characteristic is preferred.

[0063]As a solvent which makes thermoplastics plasticize, a tetrahydrofuran (THF), methyl ethyl ketone (MEK), etc. are suitable to VCM/PVC system resin, and THF, MEK, dimethylacetamide, dimethyl sulfoxide, etc. are suitable to urethane system resin. The solution solvent of thermoplastics is the solution which dissolved the above-mentioned thermoplastics with the solvent.

For example, when using THF as a solvent, using polyurethane as thermoplastics, it is preferred that polyurethane uses the solution contained five to 20% of the weight.

The viscosity of this solvent solution is preferably adjusted to 1000 - 5000cp beforehand 100 to 10000 cp. Thus,

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in the distal end of the fabricated balloon part 4. As shown in drawing 4, the tapered shape reducing part 4c and the distal end seal part 7 which change with a taper are fabricated by one, and as shown in drawing 4 in the proximal edge of the balloon part 4, a taper, the tapered shape reducing part 4b which changes, and the proximal edge seal part 5 are fabricated by one.

[0064]Next, the 1st joining section 5a in the proximal edge seal part 5 of the balloon part 4 is joined to the distal end periphery of the 1st outer tube member 6a. On the occasion of the junction, a mandrel is inserted into the distal end of the 1st outer tube member 6a.

Then, the 1st joining section 5a in the proximal edge seal part 5 of the balloon part 4 is overlapped on the periphery of the distal end of the member 6a.

And the distal end of the 1st outer tube member 6a is made to carry out thermal melting arrival of the 1st joining section 5a by covering the periphery of the 1st joining section 5a with a heat-resistant film, and heating the heat-resistant film with a metallic mold etc. although cooking temperature in particular is not limited -- desirable -- 100-300degreeC -- it is 150-250degreeC especially preferably.

[0065]As a heat-resistant film, a fluorocarbon resin tube is used, for example, and the shaft-orientations length has a long time more preferred than the 1st joining section 5a, for example, is about 20 mm. Slitting about 3 mm in length may be formed in the axial end of a tube. It is for making a heat-resistant film easy to remove after thermal melting arrival.

[0066]Then, as shown in the tube wall of the shaft-orientations prescribed position of the 1st outer tube member 6a at drawing 4, the breakthrough 21 which is a grade through which the inner tube 12 passes is formed.

[0067]Next, the inner tube 12 equipped with the imaging ring 15 is prepared. By this embodiment, in order to equip the inner tube 12 with the imaging ring 15, as first shown in drawing 7, the position which is [prescribed distance Lt] separated from the distal end of the inner tube 12 is held with a finger etc. via the non skid sheet 50, and pliers etc. pull the distal end of the inner tube 12 to an arrow direction. As a result, some outer diameters of the inner tube 12 of the range of the prescribed distance Lt become small. A rubber sheet is used as the non skid sheet 50. As the prescribed distance Lt, it is 3-10 mm, for example.

[0068]Next, the portion pinched with pliers etc. is deleted with a razor etc., the mandrel for shape restoration is inserted in the distal end of the inner tube 12, and the portion of the inner tube which changed flatly is returned to a round cross section. Then, the mandrel for shape restoration is drawn out and the mandrel 54 for drawing processing shown in drawing 8 is instead inserted into the distal end of the inner tube 12. In the state, the distal end of the inner tube 12 is drawn out to the circular hole of the die 52 for drawing processing, through, the pliers 56, etc. draw out the distal end of the inner tube 12, and it is processed. The die 52 is heated, for example at 40-80 **.

[0069]As a result, the diameter of the outer diameter of the inner tube 12 is reduced from the original outer diameter D1, and the diameter reduction part 58 of the outer diameter D2 is formed. The inside diameter of the diameter reduction part 58 in the inner tube 12 maintains the inside diameter of the original inner tube 12 for the mandrel 54. As for the outer diameter D2 of the diameter reduction part 58 shown in drawing 8, it is preferred that it is $D2/D1=0.8-0.95$ to the original outer diameter D1. As for the thickness T2 of the diameter reduction part 58, it is preferred that $T2/T1$ becomes the relation between 0.6-0.9 to the original thickness T1 of the inner tube 12 shown in drawing 9.

[0070]As for the outer diameter D2 of the diameter reduction part 58, it is preferred that it is an inside diameter of the imaging ring 15 and below equivalent. It is for making the periphery of the diameter reduction part 58 equipped with the mandrel 54 equip with the imaging ring 15 easily, as shown in drawing 9. According to this embodiment, while is arranged at the proximal edge side, the imaging ring 15 is attached to the position of the level difference part which moves from the original outer diameter of the inner tube 12 to the diameter reduction part 58, and the imaging ring 15 of another side is attached to the position of the prescribed distance Ls shown in drawing 4 from the imaging ring 15.

[0071]In the state, the diameter reduction part 58 in the inner tube 12 is heated with prescribed temperature. As for the prescribed temperature, it is preferred that there is about 7-15 ** about 5-20 ** in the range by the side of low temperature preferably from the melting point of the synthetic resin which constitutes the inner tube 12. For example, as for cooking temperature, when the inner tube 12 comprises polyethylene, it is preferred that it is 120**5 **.

[0072]As a result of heating the diameter reduction part 58 in the inner tube 12, as shown in drawing 6, the outer diameter of the diameter reduction part 58 can revert, and the imaging ring 15 can be fixed to the prescribed position of the inner tube 12. It becomes same the outer diameter D1 of the original inner tube 12 and omitting the outer diameter D4 of the inner tube 12 after restoration. For example, the diameter reduction part 58 can be restored so that $D4/D1$ may become the range of 0.9-1.

[0073]The ratios $D4/D5$ of the outer diameter $D4$ of the inner tube after the restoration to the outer diameter $D5$ of the imaging ring 15 are 0.7–1 preferably. The ratios $D4/D3$ of the outer diameter $D4$ of the inner tube 12 after the restoration to the inside diameter $D3$ of the imaging ring 15 are 1–1.2 preferably.

[0074]Thus, after manufacturing the inner tube 12 in which the prescribed position of the distal end of the inner tube 12 was equipped with the imaging ring 15 of the couple, the inside of the balloon part 4 which shows drawing 4 the inner tube 12 as follows is equipped.

[0075]First, it unifies through a wire-like mandrel in the lumen of the inner tube 12. The distal end of through and the inner tube 12 is made for the inner tube 12 in which the mandrel was unified to project from the distal end seal part 7 of the balloon part 4 in the inner lumen of the breakthrough 21 to the 1st outer tube member 6a, and each imaging ring 15 is located in intersection 4ab and 4ac of the balloon part 4. Before and after that, the tube for heat sealing is located at the periphery of the 1st outer tube member 6a.

[0076]Then, the mandrel for heat sealing is inserted in an inside from the proximal end part of the 1st outer tube member 6a, the tip part of a mandrel is located near the breakthrough 21, and crushing of the 1st outer tube 6a near the breakthrough 21 is prevented. The base end of a mandrel is the same in the inside diameter of the 1st outer tube member 6a, and abbreviation, or it has an outer diameter not more than it, and the shaft-orientations crevice is formed in the tip part so that the periphery of the inner tube 12 may be received. Next, the tube for heat sealing is moved to shaft orientations on the periphery of the 1st outer tube member 6a, and the tube for heat sealing covers in one the periphery of the 1st outer tube 6a near the breakthrough 21, and the outside of the inner tube 12 which jumps out of the breakthrough 21. Then, using a heat-sealing public-funds type, press heating is carried out from the outside of the tube for heat sealing, and thermal melting arrival of the hole edge of the breakthrough 21 and the outside tube wall of the inner tube 12 is carried out. although cooking temperature in particular is not limited -- desirable -- 100–300degreeC -- it is 150–250degreeC especially preferably.

[0077]Then, a mandrel is taken out and the tube for heat sealing is removed. Then, it leaves the heat sealed part of the outside tube wall of the inner tube 12 and the common-law marriage of the breakthrough 21 by which it is as thermal melting commencement of work, and thermal melting arrival was carried out, and a cutter etc. cut and remove the garbage of the inner tube 12 located outside from the heat sealed part concerned. As a result, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the tube wall of the 1st outer tube member 6a, and is formed. The proximal edge opening 22 serves as an approximately elliptical in this example.

[0078]Before and after being these processes, simultaneously, to the distal end seal part 7 of the balloon part 4, thermal melting arrival of the distal end of the inner tube 12 is carried out by the same heat seal method, and it is processed so that the tip taper part 7a may be formed. Details are shown below.

[0079]First, as shown in drawing 10, the distal end of the inner tube 12 is inserted in the inside of the distal end seal part 7 of the balloon part 4, and the mandrel 40 is inserted in the inside of through and the inner tube 12 from the distal end. Then, the periphery of the distal end seal part 7 of the balloon part 4 is covered with the heat-resistant film 41 by the position corresponding to the 2nd joining section 12a of the inner tube 12, and the heat-resistant film 41 is heated with the metallic mold 43. As a result, in the fuse section 44 corresponding to the shaft-orientations length of the heat-resistant film 41, thermal melting arrival of the distal end seal part 7 of the balloon part 4 is carried out to the periphery of the inner tube 12. At the time of thermal melting arrival, the balloon 4 is wound around the surroundings of the inner tube 12, and is folded up, and the periphery is protected by a protective tubing etc. A heat-resistant fluorocarbon resin tube is used as a protective tubing.

[0080]the thermal melting arrival in the proximal edge seal part 5 of the balloon part 4 although the cooking temperature in particular at the time of thermal melting arrival is not limited -- the same -- desirable -- 100–300degreeC -- it is 150–250degreeC especially preferably. As the heat-resistant film 41, a fluorocarbon resin tube is used, for example and slitting about 3 mm in length may be formed in the axial end of a tube. It is for making the heat-resistant film 41 easy to remove after thermal melting arrival.

[0081]In the fuse section 44, after the distal end seal part 7 removes the metallic mold 43, removes the heat-resistant film 41 and removes the mandrel 40 after thermal melting arrival on the periphery of the inner tube 12, the garbage 7b by the side of the tip in the distal end seal part 7 is removed. Since the non-fused part 46 is formed in the distal end side of the fuse section 44 in the distal end seal part 7 when removing the garbage 7b, it is easily removable with a cutter etc. Then, the tip tapered surface 7a of the distal end seal part 7 is forced on the surface of revolution of the rotation disks for polish, for example, and polishing work is carried out so that the smooth tip taper part 7a may be formed. Then, as shown in drawing 5, the distal end of the inner tube 12 is cut to the predetermined length L_f , chamfering work of the cutting plane is carried out, and the tapered surface 12c is formed.

[0082]Then, the distal end of the 2nd outer tube part 6b is joined to the proximal end part of the 1st outer tube

member 6a. On the occasion of the junction, first, the tube for heat sealing is put on the periphery of the 2nd outer tube member 6b, and the distal end of the 2nd outer tube member 6b is stuffed into it in the lumen of the proximal end part of the 1st outer tube 6a. then, the 2nd outer tube member 6b — a mandrel is inserted in the inside of 24 along shaft orientations, and the 3rd lumen of the tip is made to project to the inside of the 1st outer tube member 6a. You make it located in the order or coincidence to lower [of the proximal edge opening 22 of the 2nd outer tube member 6b which inserts the 4th lumen of the reinforcing rod 28 in the inside of 26 along shaft orientations, and has formed the tip part in the periphery of the 1st outer tube member 6a].

[0083] Then, the tube for heat sealing is moved to shaft orientations, the joined part 9 of the 1st outer tube member 6a and the 2nd outer tube member 6b is covered by this tube for heat sealing, and thermal melting arrival is performed on the heat-sealing conditions mentioned above and the same heat-sealing conditions using a metallic mold.

[0084] Then, the tube for heat sealing is removed, and a mandrel is removed and the connector 8 shown in drawing 1 is joined to the proximal end part of the 2nd outer tube member 6b by thermal melting arrival or other means. Then, the covering material which comprises the hydrophilic polymer material which has lubricity in the peripheral face of the outer tube 6 by a damp or wet condition is covered if needed, and the balloon catheter 2 shown in drawing 1 is obtained.

[0085] Next, how to perform a PTCA therapy is explained using the balloon catheter 2 of the embodiment shown in drawing 1. First, the air in the balloon catheter 2 is removed as much as possible. Then, suction and injection means, such as a syringe, are attached to the port of the connector 8, fluids, such as a blood contrast medium (for example, iodine content), are put in in a syringe, suction and pouring are repeated, and the 3rd lumen of the air in 24, and 1st lumen 10 and the balloon part 4 is replaced by a fluid.

[0086] In order to insert the balloon catheter 2 into an arterial blood pipe, the guidewire for guide catheters (not shown) is first inserted into a blood vessel by Seldinger method etc. so that the tip may arrive to near the heart. Then, along with the guidewire for guide catheters, a guide catheter is inserted into an arterial blood pipe, and the tip is located in the coronary artery entrance of the heart which has a narrow segment. A narrow segment is formed, for example of a thrombus or arteriosclerosis.

[0087] Next, only the guidewire for guide catheters is sampled, the guidewire for balloon catheters thinner than it is inserted along with a guide catheter, and the tip is inserted to the position which passes a narrow segment.

[0088] Then, the distal end of a guidewire is inserted in the distance open end 20 of the balloon catheter 2 shown in drawing 1, and is pulled out from through and the proximal edge opening 22 in 1st lumen 14. And where the balloon part 4 is folded up, along with the guidewire 42, it lets the balloon catheter 2 pass in a guide catheter. And as shown in drawing 11, the balloon part 4 of the balloon catheter 2 is inserted to this side of the narrow segment 36 in the blood vessel 34.

[0089] Then, the balloon part 4 by which the balloon catheter 2 was folded up is inserted between narrow segments along with a guidewire. Next, the balloon part 4 is correctly located in the center section of the narrow segment, observing the position of the balloon part 4 with an X-ray fluoroscope etc. By swelling the balloon part 4 in the position, the narrow segment of a blood vessel can be extended and a good therapy can be performed. In order to swell the balloon part 4, the 3rd lumen is performed from the port of the connector 8 shown in drawing 1 24 and by letting 10 [lumen / 1st] pass and pouring in a fluid into the balloon part 4.

[0090] Although this expansion time in particular is not limited, it is a for [about 1 minute] grade, for example. Then, a fluid is promptly drained from the balloon part 4, a balloon part is shrunk, and the blood flow by the side of the tip of the extended narrow segment is secured. It is necessary to perform extension of a narrow segment gradually, it inserts the balloon catheter 2 which has the balloon part 4 of a small outer diameter at first along with a guidewire, and exchanges it for the balloon catheter 2 with the balloon part 4 of a big outer diameter one by one so that a blood vessel may not be damaged. The balloon catheter 2 applied to this embodiment in that case, Since it is a balloon catheter of a monorail method, clearing work of a balloon catheter can be performed only by extending the proximal end part of the guidewire 42 at the outside-of-the-body side to the grade slightly longer than the portion equivalent to the length of the inner tube 12.

[0091] In the balloon catheter 2 concerning this embodiment, the catheter tube structure of what is called coaxial structure which comprises the outer tube 6 and the inner tube 12 only in the distal end of the balloon catheter 2 is adopted, and the lumen 14 of the inner tube 12 is used as a lumen for guidewire insertion. For this reason, as compared with the conventional balloon catheter (JP,S63-288167,A and JP,H2-307479,A) which has the so-called catheter tube of a double lumen, it is easy to make thin the outer diameter of the 1st outer tube member 6a with the balloon catheter 2 concerning this embodiment. In the balloon catheter 2 concerning this embodiment. The proximal edge opening 22 of the inner tube 12 used as the proximal edge side output port of a guidewire, The tube wall located in the middle of the longitudinal direction of the outer tube 6 is penetrated, and the opening is carried out outside, and in the opening 22, it becomes the dual structure of the inner tube 12 and

the outer tube 6, and has structure which cannot carry out a kink easily.

[0092]In the balloon catheter 2 furthermore applied to this embodiment. The proximal edge opening 22 of the inner tube 12 used as the proximal edge side output port of the guidewire 42, It is not necessary to cover the overall length of the catheter tube 2 and to make a level difference, and the tube wall located in the middle of the longitudinal direction of the outer tube 6 is penetrated, and it is only carrying out the opening outside and excels in the insertion characteristic of the balloon catheter 2. Since it is the structure which cannot carry out a kink easily, it excels also in the pushing characteristic of the balloon catheter 2.

[0093]In this embodiment, as shown in drawing 2, since the reinforcing rod 28 is arranged from the opening 22 neighborhood inside the 1st outer tube member 6a by the side of a proximal edge, the pushing characteristic of a balloon catheter improves further, and. The distal end side of a catheter tube becomes flexible, and the insertion characteristic within the abdominal cavities, such as a blood vessel which wound, improves further.

[0094]Furthermore, by this embodiment, since the distal end 28a of the reinforcing rod 28 is not being fixed to the wall of the 1st outer tube member 6a, Even when a branching portion inserts the balloon catheter 2 in many [and] thin blood vessels like a coronary artery, the distal end of the 1st outer tube member 6a transforms it flexibly corresponding to the crooked part of a blood vessel. This is considered because it can change freely, without restricting the distal end of the 1st outer tube member 6a to the reinforcing rod 28, since the distal end 28a of the reinforcing rod 28 is not being fixed to the wall of the 1st outer tube member 6a.

[0095]By this embodiment, the proximal edge seal part 5 of the balloon part 4 has further again a part for the 1st non-connecting part 5b that does not overlap with the 1st joining section 5a joined to the distal end of the outer tube part 6 by overlapping. Although the amount of [in the proximal edge seal part 5 of the balloon part 4 / 5b] 1st non-connecting part is a portion which hardly contributes to the curative effect by extension of the balloon part 4, its pliability in the distal end of the balloon catheter 2 improves by providing the portion. The amount of [5b] 1st non-connecting part is a part of balloon part 4.

It is because it is supple rather than the outer tube part 6.

[0096]Therefore, even when a branching portion inserts the balloon catheter 2 of this embodiment in many [and] thin blood vessels like a coronary artery, the distal end of the balloon catheter 2 transforms it flexibly corresponding to the crooked part of a blood vessel. That is, in the balloon catheter 2 of this embodiment, the insertion characteristic and the pushing characteristic of the balloon catheter 2 improve.

[0097]According to this embodiment, the tip taper part 7a to which an outer diameter becomes thin towards the distal end periphery of the inner tube 12 is formed in the distal end seal part 7 of the balloon part 4 joined to the distal end of the inner tube 12. And a part for the 2nd non-connecting part 12b to which the distal end seal part 7 of the balloon part 4 is not joined is formed in the distal end periphery of the inner tube 12.

[0098]For this reason, as shown in drawing 11, it is possible for the outer diameter of the distal end of the balloon catheter 2 to become equal to the outer diameter of the inner tube 12, and to insert the distal end of the balloon catheter 2 easily also to the narrow segment 36 of the blood vessel 34 which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of the balloon catheter 2 improves.

[0099]Especially, by this embodiment, since the diameter reduction part 58 which makes the diameter of the outer diameter of the inner tube 12 of the predetermined length range including the position equipped with the imaging ring 15 reduce compulsorily, and has an inside diameter of the imaging ring 15 and an outer diameter below equivalent is formed, The work which equips the diameter reduction part 58 of the inner tube 12 with the imaging ring 15 is easy. The outer diameter of the diameter reduction part 58 is restored to near the original outer diameter by equipping the diameter reduction part 58 with the imaging ring 15, and heating after that. Therefore, as shown in drawing 6, the imaging ring 15 serves as structure embedded on the periphery of the inner tube 12, and is fixed to the prescribed position.

[0100]Thus, the manufactured balloon catheter 2 serves as the structure where the imaging ring 15 is embedded on the periphery of the inner tube 12, and it is lost in the fixing point of the imaging ring 15 that the imaging ring 15 projects of it too much from the periphery of the inner tube 12. As a result, it is in the state which folded up the balloon part 4 on the periphery of the inner tube 12, and it is possible to become possible to make the outer diameter small, and to insert the distal end of the balloon catheter 2 easily also to the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of the balloon catheter 2 improves.

[0101]In the manufacturing method of the balloon catheter concerning this embodiment. boiling a balloon catheter comparatively -- 2 -- it can manufacture easily, and the bonding strength of the imaging ring 15 and the inner tube 12 also comes out enough, and there is, and, moreover, it is hard to produce defects, like an inner tube becomes thin meat to a degree very much etc. on the occasion of the manufacture. On the occasion of junction to the imaging ring 15 and the inner tube 12, adhesives etc. are not necessarily needed.

[0102]this invention is not limited to the embodiment mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, in the embodiment mentioned above, although the outer tube 6 was constituted from the 1st outer tube member 6a and the 2nd outer tube member 6b, it is also possible to constitute the outer tube 6 from this invention by the single tube which follows shaft orientations. The use of the balloon catheter concerning this invention is not limited to the use mentioned above.

[0103]This invention can be applied not only to a balloon catheter but to the medical device in which the metal ring (it corresponds to the imaging ring 15 in the above-mentioned embodiment) used for the periphery of a tube as an electrode, a sensor, etc. is attached. As a medical device in which an electrode is attached to the periphery of a tube, an electrode catheter etc. are illustrated, for example.

[0104]

[Effect of the Invention]The medical device which according to this invention could make small the outer diameter of the tube portion to which a metal ring is attached as much as possible, and was excellent in the insertion nature into the abdominal cavity as explained above, The manufacturing method of the medical device which can be manufactured very easily can be provided without making a tube produce a defect for the medical device.

[0105]According to this invention, the narrow segment of the blood vessel which wound when the grade of strangulation is intense is also received especially, The balloon catheter which can insert the distal end of a balloon catheter easily and was excellent in the insertion characteristic, The manufacturing method of the balloon catheter which can be manufactured very easily can be provided without making an inner tube produce a defect for the balloon catheter.

[Translation done.]

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TECHNICAL FIELD

[Field of the Invention]This invention relates to medical devices, such as a balloon catheter, and the manufacturing method of those, and relates to the medical device in which the imaging ring for the medical device in which the metal ring used as an electrode, a sensor, etc. is attached in more detail, or X ray imaging is attached, and its manufacturing method.

[0002]

[Translation done.]

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PRIOR ART

[Description of the Prior Art]In recent years, the iatrotechnique tends to go to a low invasion therapy. For example, instead of a former coronary-bypass operation, a measure is being taken more often with the balloon catheter for vasodilatation by strangulation of coronary arteries. This therapeutic method has expanded the scope increasingly, in order to ease a patient's burden greatly with an economical advantage. The structure of the balloon catheter used for strangulation extension of still more efficient and easy coronary arteries with it is searched for.

[0003]As what is called a PTCA balloon catheter for inserting into a blood vessel, extending a narrow segment by swelling a balloon part, and aiming at an improvement of the blood flow by the side of a narrow segment tip, in order to treat an intravascular narrow segment, There are a balloon catheter of an excess the wire method and a balloon catheter (for example, JP,2000-217923,A) of a monorail method. In the balloon catheter of these methods, a guidewire is previously passed to an intravascular narrow segment, then, each sends in a balloon catheter to a narrow segment along with this guidewire, and a narrow segment is extended by swelling a balloon part.

[0004]The inside of the outer tube which constitutes a catheter tube in the conventional balloon catheter has many by which an inner tube is arranged, using such a PTCA balloon catheter as the start. It was used as a guidewire insertion hole, thermal melting arrival of the distal end of a balloon part was carried out to the periphery of the distal end of an inner tube, and the lumen of an inner tube has sealed the inside of a balloon part.

[0005]In the conventional balloon catheter, in order to grasp the position of the PTCA balloon catheter inserted into the blood vessel, the imaging ring which comprised tungsten etc. is attached to the periphery of the inner tube located in the inside of a balloon part. Generally, since an imaging ring is inserted in from the outside of an inner tube, the outer diameter of the portion becomes larger than the outer diameter of an inner tube, and the shape of an inner tube becomes a convex extremely. For this reason, when it is going to pass the balloon catheter in the state where the balloon part was folded up, to the strangulation portion of a blood vessel, it is possible to become an obstacle.

[0006]As shown in JP,H8-289934,A, a concave is provided in the prescribed position of an inner tube by processing means, such as etching, and the structure which attached the imaging ring to the concave is proposed. However, in the balloon catheter of this structure, when forming a concave in the periphery of the inner tube of thin meat extremely, the thickness of an inner tube changes too much thinly, and it is easy to produce a defect in an inner tube. After processing a concave into an inner tube, it is difficult to attach an imaging ring to the concave.

[0007]In medical devices other than a balloon catheter, there is a medical device in which the metal ring used as an electrode, a sensor, etc. in addition to the use of an imaging ring etc. is attached to the periphery of the tube made of a synthetic resin, and it has the same inconvenience as a balloon catheter also in this case.

[Translation done.]

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EFFECT OF THE INVENTION

[Effect of the Invention]The medical device which according to this invention could make small the outer diameter of the tube portion to which a metal ring is attached as much as possible, and was excellent in the insertion nature into the abdominal cavity as explained above, The manufacturing method of the medical device which can be manufactured very easily can be provided without making a tube produce a defect for the medical device.

[0105]According to this invention, the narrow segment of the blood vessel which wound when the grade of strangulation is intense is also received especially, The balloon catheter which can insert the distal end of a balloon catheter easily and was excellent in the insertion characteristic, The manufacturing method of the balloon catheter which can be manufactured very easily can be provided without making an inner tube produce a defect for the balloon catheter.

[Translation done.]

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]In view of such the actual condition, accomplish this invention, and the purpose of this invention, It is providing the manufacturing method of the medical device which could make small the outer diameter of the tube portion to which a metal ring is attached as much as possible, and was excellent in the insertion nature into the abdominal cavity, and the medical device for which the medical device can be manufactured very easily without making a tube produce a defect.

[0009]The 2nd purpose of this invention also receives the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially. The balloon catheter which can insert the distal end of a balloon catheter easily and was excellent in the insertion characteristic, It is providing the manufacturing method of the balloon catheter which can be manufactured very easily, without making an inner tube produce a defect for the balloon catheter.

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MEANS

[Means for Solving the Problem]In order to attain the 1st purpose of the above, a medical device concerning this invention, The diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring is made to reduce compulsorily. After forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, by equipping said diameter reduction part with a metal ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said metal ring is fixed to a prescribed position of said tube.

[0011]Preferably, ratios of an outer diameter of said tube after restoration to an outer diameter of said metal ring are 0.7-1.

[0012]Preferably, ratios of an outer diameter of said tube after restoration to an inside diameter of said metal ring are 1-1.2.

[0013]A manufacturing method of a medical device concerning this invention makes the diameter of an outer diameter of a synthetic resin tube of a predetermined length range including a position equipped with a metal ring reduce compulsorily. After forming a diameter reduction part with an inside diameter of said metal ring, and an outer diameter below equivalent, by equipping said diameter reduction part with a metal ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said metal ring is fixed to a prescribed position of said tube.

[0014]Preferably, the cooking temperature of said diameter reduction part is about 5-20 ** in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said tube.

[0015]Preferably, said diameter reduction part is formed by pulling a distal end of said tube to shaft orientations.

[0016]Preferably, it is in a state where a mandrel was inserted in an inside of a lumen of said tube, and said diameter reduction part is formed.

[0017]In order to attain the 2nd purpose of the above, a balloon catheter concerning this invention, An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal edge seal part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, An inner tube which a distal end seal part of a balloon part is joined to a distal end of an inner tube, and extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, At least one imaging ring with which a peripheral part of said inner tube located in an inside of said balloon part was equipped, Are a balloon catheter which *** and the diameter of an outer diameter of an inner tube of a predetermined length range including a position equipped with said imaging ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, by equipping said diameter reduction part with an imaging ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said imaging ring is fixed to a prescribed position of said inner tube.

[0018]Preferably, ratios of an outer diameter of said inner tube after restoration to an outer diameter of said imaging ring are 0.7-1.

[0019]Preferably, ratios of an outer diameter of said inner tube after restoration to an inside diameter of said imaging ring are 1-1.2.

[0020]A manufacturing method of a balloon catheter concerning this invention, An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal edge seal part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, An inner tube which a distal end seal part of a balloon part is joined to a distal end of an inner tube, and extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, At least one imaging ring with which a peripheral part of said inner tube located in an inside of said balloon part was

equipped, The diameter of an outer diameter of an inner tube of a predetermined length range which is a manufacturing method of a balloon catheter which **** and includes a position equipped with said imaging ring is made to reduce compulsorily, After forming a diameter reduction part with an inside diameter of said imaging ring, and an outer diameter below equivalent, by equipping said diameter reduction part with at least one imaging ring, and heating after that, an outer diameter of said diameter reduction part is restored, and said imaging ring is fixed to a prescribed position of said inner tube.

[0021] Preferably, the cooking temperature of said diameter reduction part is about 5-20 ** in a range by the side of low temperature from the melting point of a synthetic resin which constitutes said inner tube.

[0022] Preferably, said diameter reduction part is formed by pulling a distal end of said inner tube to shaft orientations.

[0023] Preferably, it is in a state where a mandrel was inserted in an inside of a lumen of said inner tube, and said diameter reduction part is formed.

[0024]

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OPERATION

[Function]Since the diameter reduction part which makes the diameter of the outer diameter of the synthetic resin tube of the predetermined length range which includes the position equipped with a metal ring in the manufacturing method of the medical device concerning this invention reduce compulsorily, and has an inside diameter of a metal ring and an outer diameter below equivalent is formed, the work which equips the diameter reduction part of a tube with a metal ring is easy. The outer diameter of said diameter reduction part is restored to near the original outer diameter by equipping the diameter reduction part with a metal ring, and heating after that. Therefore, a metal ring serves as structure embedded on the periphery of an inner tube, and is fixed to the prescribed position.

[0025]Thus, the manufactured medical device serves as the structure where a metal ring is embedded on the periphery of an inner tube, and it is lost in the fixing point of the metal ring that a metal ring projects of it too much from the periphery of a tube. As a result, it becomes possible to make small the outer diameter of the portion equipped with a metal ring, and the insertion characteristic of a medical device improves.

[0026]The medical device concerning this invention can be easily manufactured in comparison, and the manufacturing method of the medical device concerning this invention is enough also as the bonding strength of a metal ring and a tube, and, moreover, it is hard to produce defects, like a tube becomes thin meat to a degree very much etc. in it on the occasion of the manufacture. On the occasion of junction in a metal ring and a tube, adhesives etc. are not necessarily needed.

[0027]In the manufacturing method of the balloon catheter concerning this invention. Since the diameter reduction part which makes the diameter of the outer diameter of the inner tube of the predetermined length range including the position equipped with an imaging ring reduce compulsorily, and has an inside diameter of said imaging ring and an outer diameter below equivalent is formed, the work which equips the diameter reduction part of an inner tube with an imaging ring is easy. The outer diameter of said diameter reduction part is restored to near the original outer diameter by equipping the diameter reduction part with an imaging ring, and heating after that. Therefore, an imaging ring serves as structure embedded on the periphery of an inner tube, and is fixed to the prescribed position.

[0028]Thus, the manufactured balloon catheter serves as the structure where an imaging ring is embedded on the periphery of an inner tube, and it is lost in the fixing point of the imaging ring that an imaging ring projects of it too much from the periphery of an inner tube. As a result, it is in the state which folded up the balloon part on the periphery of the inner tube, and it is possible to become possible to make the outer diameter small, and to insert the distal end of a balloon catheter easily also to the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of a balloon catheter improves.

[0029]The balloon catheter concerning this invention can be easily manufactured in comparison, and the manufacturing method of the balloon catheter concerning this invention is enough also as the bonding strength of an imaging ring and an inner tube, and, moreover, it is hard to produce defects, like an inner tube becomes thin meat to a degree very much etc. in it on the occasion of the manufacture. On the occasion of junction to an imaging ring and an inner tube, adhesives etc. are not necessarily needed.

[0030]

[Embodiment of the Invention]Hereafter, this invention is explained based on the embodiment shown in Drawings. The balloon catheter 2 concerning this embodiment shown in drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this embodiment is used for PTCA.

[0031]The balloon catheter 2 for extension of this embodiment is the so-called balloon catheter of a monorail

method.

It has the balloon part 4, the outer tube 6 as a catheter tube, the inner tube 12, and the connector 8.

[0032]The balloon part 4 shown in drawing 1 and drawing 4, has the cylindrical section 4a which has a bigger outer diameter than the outer diameter of the outer tube 6 in the state where it swelled. The tapered shape reducing parts 4b and 4c which follow the both ends of the cylindrical section 4a at it, and the proximal edge seal part 5 and the distal end seal part 7 which follow them, respectively are fabricated to one. The proximal edge seal part 5 has an outer diameter smaller than the cylindrical section 4a so that it may be connected to the distal end peripheral part of the outer tube 6. The distal end seal part 7 has an outer diameter smaller than the proximal edge seal part 5 so that it may be connected to the distal end peripheral part of the inner tube 12.

[0033]Although the thickness in particular of the balloon part 4 is not limited, it is 30–150 micrometers preferably 15–300 micrometers. As long as the cylindrical section 4a of the balloon part 4 is cylindrical, it may not be limited in particular but a cylinder or the shape of a multiple cartridge may have as it. The outer diameter of the balloon part 4 at the time of extension is determined by factors, such as an inside diameter of a blood vessel, and is usually 3–7 mm preferably about 1.5–10.0 mm. Although the shaft-orientations length of the cylindrical section 4a in this balloon part 4 is determined by factors, such as a size of an intravascular narrow segment, and is not limited in particular, it is 20–40 mm preferably 15–50 mm. The balloon part 4 before extending is folded up around the inner tube 12, and is twisted, and the outer diameter is small as much as possible.

[0034]As for the construction material which constitutes the balloon part 4, it is preferred that it is the construction material which has a certain amount of flexibility. For example, polyethylene, polyethylene terephthalate, polypropylene, The copolymer of ethylene, such as ethylene propylene rubber, and other alpha olefins, An ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), the constructed type ethylene-vinylacetate copolymer of a bridge, Polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and they are polyethylene, polyethylene terephthalate, and polyamide preferably. By introducing a fluid into an inside, the balloon part 4 comprises construction material and thickness more flexible than the tubes 6 and 12 so that it can swell or fade.

[0035]the 1st joining section 5a joined by the proximal edge seal part 5 of the balloon part 4 overlapping with the distal end of the outer tube 6 as shown in drawing 4, and this 1st joining section 5a — abbreviated — it has a part for the 1st non-connecting part 5b that does not overlap with the distal end of the outer tube 6 with the same outer diameter. having joined the 1st joining section 5a to the distal end periphery of the outer tube 6 by thermal melting arrival, adhesion, or other means — the outer tube 6 — 10 [lumen / 1st] is open for free passage with the space for internal extension of the balloon part 4. The distal end seal part 7 of the balloon part 4 is joined by thermal melting arrival, adhesion, or other means to the distal end periphery of the inner tube 14, and the space for internal extension of the balloon part 4 is sealed to the exterior except 1st lumen 10. It is a passage for [of the outer tube 6] 10 sending the 1st lumen of a fluid into the internal growth space of the balloon part 4, and making the balloon part 4 extend, or sampling a fluid from the growth space of the balloon part 4, and shrinking the balloon part 4.

[0036]According to this embodiment, in the proximal edge seal part 5 of the balloon part 4, the ratio (La:Lb) of shaft-orientations length La of the 1st joining section 5a and the shaft-orientations length Lb for the 1st non-connecting part 5b is in the range of 1:2–1:5 preferably in 1:1–1:10, and a pan. Shaft-orientations length La of the 1st joining section 5a is 2–5 mm preferably. The shaft-orientations length Lb for the 1st non-connecting part 5b is 15–20 mm preferably. It is in the tendency for junction to become insufficient if shaft-orientations length La of the 1st joining section 5a is too short, and when too long, the length of areas of overlap becomes long and it is in the tendency for the pliability in the portion to fall. It is in the tendency to have the same inconvenience as the conventional balloon catheter when the shaft-orientations length Lb for the 1st non-connecting part 5b is too short, and when too long, it is in the tendency for the intensity of the balloon part 4 to fall. The overall length Lc of the proximal edge seal part 5 is 17–25 mm preferably.

[0037]As shown in drawing 4, as for the growth space [of the balloon part 4], and distal end side of the outer tube 6, the 1st lumen of the inner tube 12 is extended to shaft orientations in the shape of the same axle in the inside of 10, and has the so-called catheter tube structure of coaxial structure. The periphery of the inner tube 12 located in the inside of the balloon part 4 is equipped with the imaging ring 15 of the couple, and when inserting the balloon catheter 2 in the living body, imaging is possible about the position of the imaging ring 15 through a living body's exterior to X-rays etc. Metal, such as gold, platinum, and tungsten, is illustrated as construction material of the imaging ring 15.

[0038]The shaft-orientations length Lr of each imaging ring 15 is 1–1.2 mm still more preferably 0.5–2 mm preferably. The distal end of the imaging ring 15 arranged at the distal end side of the balloon catheter 2 is

located in the position corresponding to intersection 4ac of the cylindrical section 4a and the tapered shape reducing part 4c in the balloon part 4. The proximal edge of the imaging ring 15 arranged at the proximal edge side of the balloon catheter 2 is located in the position corresponding to intersection 4ab of the cylindrical section 4a and the tapered shape reducing part 4b in the balloon part 4.

[0039] That is, the distance L_s from the distal end of the imaging ring 15 by the side of a distal end to the proximal edge of the imaging ring 15 by the side of a proximal edge corresponds to the length of the cylindrical section 4a. Therefore, the position of the cylindrical section 4a in the balloon part 4 can be correctly grasped by detecting the position of the imaging ring 15 of a couple through X-rays etc. This cylindrical section 4a is a portion which contributes to extension of the narrow segment produced in the blood vessel etc. These imaging rings 15 are being embedded and fixed to the periphery of the inner tube 12 as shown in drawing 6. The embedding fixing method is mentioned later.

[0040] As shown in drawing 5, the tip taper part 7a to which an outer diameter becomes thin towards the distal end periphery of the inner tube 12 is formed in the tip part of the distal end seal part 7 of the balloon part 4. The distal end of the inner tube 12 has projected to the pan of the tip taper part 7a in shaft orientations at the distal end side.

As a result, a part for the 2nd non-connecting part 12b that is not joined to the 2nd joined part 12a to which the distal end seal part 7 of the balloon part 4 is joined is formed in the distal end periphery of the inner tube 12.

[0041] According to this embodiment, in the distal end seal part 7 of the balloon part 4, the ratio ($L_d:L_e$) of the shaft-orientations length L_d of the 2nd joining section 12a and the shaft-orientations length L_e for the 2nd non-connecting part 12b is in the range of 1.5:1-3:1 preferably in 1:2-4:1, and a pan. The shaft-orientations length L_d of the 2nd joining section 12a is 1.5-3 mm preferably. The shaft-orientations length L_e for the 2nd non-connecting part 12b is 0.5-1.5 mm preferably. It is in the tendency for junction to become insufficient if the shaft-orientations length L_d of the 2nd joining section 12a is too short, and when too long, the length of a joining section becomes long and it is in the tendency for the pliability in the portion to fall. It is in the tendency to have the same inconvenience as the conventional balloon catheter when the shaft-orientations length L_e for the 2nd non-connecting part 12b is too short, and when too long, it is the futility of material, and it is in the tendency which becomes the obstacle of a therapy. The 2nd joining section 12a and the total length L_f for the 2nd non-connecting part 12b are 3.5-5.5 mm preferably. In this embodiment, the taper part 12c which also becomes a distal end periphery of the inner tube 12 with a taper is formed.

[0042] 14 [lumen / 2nd] is formed in the inside of the inner tube 12, and the opening of the distal end opening 20 is carried out to it by the distal end side rather than the distal end seal part 7 of the balloon part 4. As shown in drawing 1 and drawing 2, the proximal edge opening 22 of the inner tube 12 penetrates the breakthrough 21 of a tube wall located in the middle of the longitudinal direction of the outer tube 6, and is carrying out the opening outside. The periphery of the proximal edge opening 22 of the inner tube 12 and the periphery of the breakthrough 21 of the tube wall of the outer tube 6 are airtightly joined by the thermal melting arrival method. Although the shape in particular of the proximal edge opening 22 of the inner tube 12 is not limited but can take various shape, such as circular and an ellipse form, it is elliptical [which cut the open end of the inner tube 12 aslant] in this embodiment. The 2nd lumen turns into a lumen for guidewire insertion which the guidewire 42 shown in drawing 4 for 14 to guide [of the inner tube 12] the balloon catheter 2 into the abdominal cavity inserts in. The guidewire 42 is 0.25-0.6 mm still more preferably 0.1-1 mm preferably, although it constitutes, for example from single track or stranded wires, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, and the outer diameter in particular is not limited.

[0043] In this embodiment, the outer tube 6 The 1st outer tube member 6a of a circular section, It has the 2nd outer tube member 6b of the irregular shape cross joined to the proximal end part of the 1st outer tube member 6a concerned, and the proximal edge opening 22 of the inner tube 12 penetrates the tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and is carrying out the opening outside. Although the shaft-orientations length L_2 in particular of the 1st outer tube 6a is not limited, it is 200-300 mm still more preferably 100-400 mm preferably.

[0044] Although the 1st outer tube member 6a may comprise the same construction material as the balloon part 4, for example, It is preferred to comprise construction material which has flexibility, and For example, polyethylene, Polyethylene terephthalate, polypropylene, ethylene propylene rubber, An ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), the constructed type ethylene-vinylacetate copolymer of a bridge, Polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and it comprises polyethylene, polyamide, and polyimide preferably.

[0045] As an elastic synthetic resin which constitutes the 1st outer tube member 6a, that whose JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, is about 50A-90A preferably can be used.

[0046]Although the inner tube 12 can be constituted from soft synthetic resin of the same construction material as the 1st outer tube 6a, a hard synthetic resin may constitute it from the 1st outer tube 6a. As for the position, as for, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the 1st outer tube member 6a, it is preferred that it is a position of the distal end of the 1st outer tube member 6a to the length L1, and the length L1 is 200-300 mm still more preferably 150-350 mm preferably. Although the outer diameter in particular of the 1st outer tube member 6a is not limited, it is 0.5-1 mm still more preferably 0.5-5 mm preferably. Although the thickness in particular of the 1st outer tube member 6a is not limited, it is 0.1-0.2 mm still more preferably 0.05-0.5 mm preferably.

[0047]Although the outer diameter of the inner tube 12 is determined that a crevice is formed and is not limited in particular between the 1st outer tube members 6a, it is 0.3-0.8 mm still more preferably 0.3-3 mm preferably. Especially if the inside diameter of the inner tube 12 is a path which can insert in the guidewire 42, it will not be limited, for example, it is 0.25-0.6 mm preferably 0.15-1.0 mm.

[0048]Although the 2nd outer tube member 6b may be constituted from same construction material as the 1st outer tube member 6a, constituting from other construction material is preferred. For example, it is preferred to constitute the 1st outer tube member 6a from the 2nd outer tube member 6b with an elastic synthetic resin.

[0049]As an elastic synthetic resin which constitutes the 1st outer tube member 6a, That whose JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, is about 50A-90A preferably can be used, As a hard synthetic resin which constitutes the 2nd outer tube member 6b, JIS hardness, such as polyurethane, polyamide, polyimide, and polyethylene, can use the thing of 50D-75D.

[0050]As shown in drawing 2 (B), in this embodiment the cross section contour shape of the 2nd outer tube member 6b, The maximum sectional width x_m of the catheter tube of an X axial direction vertical to a Y-axis in the section of the outer tube member 6b which has elliptical [long and slender] in Y shaft orientations, a ratio (x_m/y_m) with the maximum sectional width y_m of Y shaft orientations is in the range of 0.8-0.1 -- the 3rd of section semicircular shapes -- lumen 24 and a round cross section -- the 4th lumen, along said Y shaft orientations, 26 dissociates and is formed.

[0051]The 3rd lumen, the cross sectional area of the semicircular shapes of 24 should just be cross sectional area sufficient in order that the pressure fluid for balloon extension may circulate, and although it is not limited in particular, it is 0.08-0.20- mm^2 preferably. The 4th lumen, the circular cross sectional area of 26 should just be area sufficient since the reinforcing rod 28 is inserted in an inside, and although it is not limited in particular, it is 0.1-0.2- mm^2 preferably [it is desirable and] to 0.05-0.5- mm^2 and a pan.

[0052]As for the maximum sectional width y_m of Y shaft orientations, in this embodiment, about 0.6-1.2 mm is preferred in the section of the 2nd outer tube member 6b. Since the distal end of the 2nd outer tube member 6b is joined to the proximal edge of the 1st outer tube member 6a of a round cross section, the lateral cross sectional shape of the joined part 9 neighborhood, In order to make it in agreement with circular section shape with the 1st outer tube member 6a, it is considered as sectional shape which changes from an irregular shape cross to a circular section gradually towards the joined part 9.

[0053]the 3rd formed along with the longitudinal direction of this 2nd outer tube member 6b -- lumen 24 -- the 1st outer tube member 6a -- the 1st lumen is open for free passage with 10, it lets these pass, and a fluid is taken in and out of the space for extension of the balloon part 4. It is a lumen for 26 to insert [of the 2nd outer tube 6b] the 4th lumen of the reinforcing rod 28.

the 1st outer tube member 6a -- although 10 [lumen / 1st] is open for free passage, the proximal edge of this lumen 26 is closed in the portion of the connector 8, and receipts and payments of a fluid are not performed. The proximal end part of the 2nd outer tube member 6b is connected with the connector 8, and the port of the 2nd outer tube 6b which is open for free passage to 24 the 3rd lumen is formed in it. The port is a portion which goes a pressure fluid in and out.

The 4th lumen is open for free passage to 26.

[0054]The reinforcing rod 28 shown in drawing 1, drawing 2 (A) - drawing 2 (C), and drawing 3, the 2nd outer tube member 6b -- the overall length was covered and it was inserted in the inside of 26, and the distal end overcame the joined part 9 with the 1st outer tube member 6a, and the 4th lumen is sticking out of it in 1st lumen 10 of the 1st outer tube member 6a. The proximal end part of the reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

The distal end 28a of the section plate-like reinforcing rod 28, As shown in drawing 1 and drawing 4, it extends to the position which also overcame slightly (preferably L about 3= 1-10 cm) the proximal edge opening 22 of the

inner tube 12, and the distal end 2a is not being fixed to the wall of the 1st outer tube member 6a.

[0055]this embodiment -- the proximal end part of the reinforcing rod 28 -- the 2nd outer tube member 6b -- it is continued and inserted in an overall length and is being fixed to the inside of 26 by the 4th lumen of the wall [the 4th lumen of] of 26 with adhesives in the range of the predetermined length L5 from the proximal edge. namely, -- while the 4th lumen of the reinforcing rod 28 is not being fixed to the wall of 26 by the distal end side at this embodiment from the position of the tube joined part 9 to the predetermined length L4 -- the 1st outer tube member 6a -- it is not being fixed to the wall of 10 by the 1st lumen. Although the predetermined length L4 and L5 in particular is not limited, it is L4=50-150mm preferably. It is L5=1000-15000mm preferably.

[0056]Although the maximum outer diameter of the reinforcing rod 28 is determined possible [the 4th lumen of the insertion to the inside of 26] for the 2nd outer tube member 6b and is not limited in particular, it is 0.3-0.6 mm preferably. The reinforcing rod 28 consists of synthetic resins, such as metallic materials, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, or polyimide, polyamide, and polyethylene terephthalate.

[0057]Especially as a pressure fluid introduced in 1st lumen 10 through the port of the connector 8, although not limited, 50/50 mixed water solution of a radiopacity medium and a physiological saline, etc. are used, for example. It is for using radiation and imaging the position of the balloon part 4 and the outer tube 6 at the time of use of the balloon catheter 2, to include a radiopacity medium. Although the pressure in particular of the pressure fluid for swelling the balloon part 4 is not limited, it is about 4-18 atmospheres preferably 3-12 atmospheres in absolute pressure.

[0058]It is preferred to have covered with this embodiment the covering material which comprises the hydrophilic polymer material which has lubricity in the periphery of the outer tube 6 which comprises the 1st outer tube member 6a and the 2nd outer tube member 6b by a damp or wet condition. By covering the periphery of the outer tube 6 with such covering material, reduction of the insertion resistance at the time of inserting the balloon catheter 2 in a blood vessel etc. can be aimed at. Although the periphery of the balloon 4 may also be covered with covering material, the balloon part 4 extends narrow segments, such as a blood vessel. When extending a narrow segment, it is not necessarily preferred that a balloon part is slippery to a narrow segment.

So, the covering material which comprises hydrophilic polymer material has covered only the periphery of the outer tube 6 in this embodiment.

[0059]As hydrophilic polymer material, there are a thing of a naturally-occurring-polymers system and a thing of a synthetic macromolecule system. As a thing of a naturally-occurring-polymers system, a starch system, a cellulose type, a tannin NIGUNIN system, a polysaccharide system, a protein system, etc. are illustrated. As a thing of a synthetic macromolecule system, a PVA system, a polyethylene oxide system, An acrylic acid series, a maleic anhydride system, a phthalate system, water soluble polyester, ketone aldehyde resin, an acrylamide (meta) system, a vinyl heterocycle system, a polyamine system, a poly electrolyte, a water-soluble nylon system, an acrylic acid glycidyl acrylate system, etc. are illustrated.

[0060]Also in these, as hydrophilic polymer material which can be conveniently used as covering material of the outer tube 6, Especially A cellulose type polymeric material (for example, hydroxypropylcellulose), A polyethylene oxide system polymeric material (for example, polyethylene glycol), A maleic anhydride system polymeric material (for example, a maleic anhydride copolymer like a methyl vinyl ether maleic anhydride copolymer), Since a low coefficient of friction is obtained by being stabilized, an acrylamide system polymeric material (for example, polydimethyl acrylamide), water-soluble nylon (for example, AQ-nylon P-70 by Toray Industries, Inc.), or those derivatives are preferred.

[0061]Next, the manufacturing method of the balloon catheter 2 concerning this embodiment is explained. First, the balloon part 4 shown in drawing 4 is formed. The balloon part 4 may be fabricated by the dipping method which dips the mandrel for balloon membrane shaping into a solution, and fabricates it, and may be fabricated by blow molding.

[0062]Especially as thermoplastics in the solution used for a dipping method, although not limited, VCM/PVC system resin, urethane system resin, amide system resin, olefin system resin, imide system resin, etc. can be illustrated, for example. Also in it, urethane system resin excellent in the bending-fatigue-resistance characteristic is preferred.

[0063]As a solvent which makes thermoplastics plasticize, a tetrahydrofuran (THF), methyl ethyl ketone (MEK), etc. are suitable to VCM/PVC system resin, and THF, MEK, dimethylacetamide, dimethyl sulfoxide, etc. are suitable to urethane system resin. The solution solvent of thermoplastics is the solution which dissolved the above-mentioned thermoplastics with the solvent.

For example, when using THF as a solvent, using polyurethane as thermoplastics, it is preferred that polyurethane uses the solution contained five to 20% of the weight.

The viscosity of this solvent solution is preferably adjusted to 1000 – 5000cp beforehand 100 to 10000 cp. Thus, in the distal end of the fabricated balloon part 4. As shown in drawing 4, the tapered shape reducing part 4c and the distal end seal part 7 which change with a taper are fabricated by one, and as shown in drawing 4 in the proximal edge of the balloon part 4, a taper, the tapered shape reducing part 4b which changes, and the proximal edge seal part 5 are fabricated by one.

[0064]Next, the 1st joining section 5a in the proximal edge seal part 5 of the balloon part 4 is joined to the distal end periphery of the 1st outer tube member 6a. On the occasion of the junction, a mandrel is inserted into the distal end of the 1st outer tube member 6a.

Then, the 1st joining section 5a in the proximal edge seal part 5 of the balloon part 4 is overlapped on the periphery of the distal end of the member 6a.

And the distal end of the 1st outer tube member 6a is made to carry out thermal melting arrival of the 1st joining section 5a by covering the periphery of the 1st joining section 5a with a heat-resistant film, and heating the heat-resistant film with a metallic mold etc. although cooking temperature in particular is not limited — desirable — 100–300degreeC — it is 150–250degreeC especially preferably.

[0065]As a heat-resistant film, a fluorocarbon resin tube is used, for example, and the shaft-orientations length has a long time more preferred than the 1st joining section 5a, for example, is about 20 mm. Slitting about 3 mm in length may be formed in the axial end of a tube. It is for making a heat-resistant film easy to remove after thermal melting arrival.

[0066]Then, as shown in the tube wall of the shaft-orientations prescribed position of the 1st outer tube member 6a at drawing 4, the breakthrough 21 which is a grade through which the inner tube 12 passes is formed.

[0067]Next, the inner tube 12 equipped with the imaging ring 15 is prepared. By this embodiment, in order to equip the inner tube 12 with the imaging ring 15, as first shown in drawing 7, the position which is [prescribed distance Lt] separated from the distal end of the inner tube 12 is held with a finger etc. via the non skid sheet 50, and pliers etc. pull the distal end of the inner tube 12 to an arrow direction. As a result, some outer diameters of the inner tube 12 of the range of the prescribed distance Lt become small. A rubber sheet is used as the non skid sheet 50. As the prescribed distance Lt, it is 3–10 mm, for example.

[0068]Next, the portion pinched with pliers etc. is deleted with a razor etc., the mandrel for shape restoration is inserted in the distal end of the inner tube 12, and the portion of the inner tube which changed flatly is returned to a round cross section. Then, the mandrel for shape restoration is drawn out and the mandrel 54 for drawing processing shown in drawing 8 is instead inserted into the distal end of the inner tube 12. In the state, the distal end of the inner tube 12 is drawn out to the circular hole of the die 52 for drawing processing, through, the pliers 56, etc. draw out the distal end of the inner tube 12, and it is processed. The die 52 is heated, for example at 40–80 **.

[0069]As a result, the diameter of the outer diameter of the inner tube 12 is reduced from the original outer diameter D1, and the diameter reduction part 58 of the outer diameter D2 is formed. The inside diameter of the diameter reduction part 58 in the inner tube 12 maintains the inside diameter of the original inner tube 12 for the mandrel 54. As for the outer diameter D2 of the diameter reduction part 58 shown in drawing 8, it is preferred that it is $D2/D1=0.8-0.95$ to the original outer diameter D1. As for the thickness T2 of the diameter reduction part 58, it is preferred that $T2/T1$ becomes the relation between 0.6–0.9 to the original thickness T1 of the inner tube 12 shown in drawing 9.

[0070]As for the outer diameter D2 of the diameter reduction part 58, it is preferred that it is an inside diameter of the imaging ring 15 and below equivalent. It is for making the periphery of the diameter reduction part 58 equipped with the mandrel 54 equip with the imaging ring 15 easily, as shown in drawing 9. According to this embodiment, while is arranged at the proximal edge side, the imaging ring 15 is attached to the position of the level difference part which moves from the original outer diameter of the inner tube 12 to the diameter reduction part 58, and the imaging ring 15 of another side is attached to the position of the prescribed distance Ls shown in drawing 4 from the imaging ring 15.

[0071]In the state, the diameter reduction part 58 in the inner tube 12 is heated with prescribed temperature. As for the prescribed temperature, it is preferred that there is about 7–15 ** about 5–20 ** in the range by the side of low temperature preferably from the melting point of the synthetic resin which constitutes the inner tube 12. For example, as for cooking temperature, when the inner tube 12 comprises polyethylene, it is preferred that it is 120**5 **.

[0072]As a result of heating the diameter reduction part 58 in the inner tube 12, as shown in drawing 6, the outer diameter of the diameter reduction part 58 can revert, and the imaging ring 15 can be fixed to the

prescribed position of the inner tube 12. It becomes same the outer diameter D1 of the original inner tube 12 and omitting the outer diameter D4 of the inner tube 12 after restoration. For example, the diameter reduction part 58 can be restored so that D4/D1 may become the range of 0.9-1.

[0073]The ratios D4/D5 of the outer diameter D4 of the inner tube after the restoration to the outer diameter D5 of the imaging ring 15 are 0.7-1 preferably. The ratios D4/D3 of the outer diameter D4 of the inner tube 12 after the restoration to the inside diameter D3 of the imaging ring 15 are 1-1.2 preferably.

[0074]Thus, after manufacturing the inner tube 12 in which the prescribed position of the distal end of the inner tube 12 was equipped with the imaging ring 15 of the couple, the inside of the balloon part 4 which shows drawing 4 the inner tube 12 as follows is equipped.

[0075]First, it unifies through a wire-like mandrel in the lumen of the inner tube 12. The distal end of through and the inner tube 12 is made for the inner tube 12 in which the mandrel was unified to project from the distal end seal part 7 of the balloon part 4 in the inner lumen of the breakthrough 21 to the 1st outer tube member 6a, and each imaging ring 15 is located in intersection 4ab and 4ac of the balloon part 4. Before and after that, the tube for heat sealing is located at the periphery of the 1st outer tube member 6a.

[0076]Then, the mandrel for heat sealing is inserted in an inside from the proximal end part of the 1st outer tube member 6a, the tip part of a mandrel is located near the breakthrough 21, and crushing of the 1st outer tube 6a near the breakthrough 21 is prevented. The base end of a mandrel is the same in the inside diameter of the 1st outer tube member 6a, and abbreviation, or it has an outer diameter not more than it, and the shaft-orientations crevice is formed in the tip part so that the periphery of the inner tube 12 may be received. Next, the tube for heat sealing is moved to shaft orientations on the periphery of the 1st outer tube member 6a, and the tube for heat sealing covers in one the periphery of the 1st outer tube 6a near the breakthrough 21, and the outside of the inner tube 12 which jumps out of the breakthrough 21. Then, using a heat-sealing public-funds type, press heating is carried out from the outside of the tube for heat sealing, and thermal melting arrival of the hole edge of the breakthrough 21 and the outside tube wall of the inner tube 12 is carried out. although cooking temperature in particular is not limited -- desirable -- 100-300degreeC -- it is 150-250degreeC especially preferably.

[0077]Then, a mandrel is taken out and the tube for heat sealing is removed. Then, it leaves the heat sealed part of the outside tube wall of the inner tube 12 and the common-law marriage of the breakthrough 21 by which it is as thermal melting commencement of work, and thermal melting arrival was carried out, and a cutter etc. cut and remove the garbage of the inner tube 12 located outside from the heat sealed part concerned. As a result, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the tube wall of the 1st outer tube member 6a, and is formed. The proximal edge opening 22 serves as an approximately elliptical in this example.

[0078]Before and after being these processes, simultaneously, to the distal end seal part 7 of the balloon part 4, thermal melting arrival of the distal end of the inner tube 12 is carried out by the same heat seal method, and it is processed so that the tip taper part 7a may be formed. Details are shown below.

[0079]First, as shown in drawing 10, the distal end of the inner tube 12 is inserted in the inside of the distal end seal part 7 of the balloon part 4, and the mandrel 40 is inserted in the inside of through and the inner tube 12 from the distal end. Then, the periphery of the distal end seal part 7 of the balloon part 4 is covered with the heat-resistant film 41 by the position corresponding to the 2nd joining section 12a of the inner tube 12, and the heat-resistant film 41 is heated with the metallic mold 43. As a result, in the fuse section 44 corresponding to the shaft-orientations length of the heat-resistant film 41, thermal melting arrival of the distal end seal part 7 of the balloon part 4 is carried out to the periphery of the inner tube 12. At the time of thermal melting arrival, the balloon 4 is wound around the surroundings of the inner tube 12, and is folded up, and the periphery is protected by a protective tubing etc. A heat-resistant fluorocarbon resin tube is used as a protective tubing.

[0080]the thermal melting arrival in the proximal edge seal part 5 of the balloon part 4 although the cooking temperature in particular at the time of thermal melting arrival is not limited -- the same -- desirable -- 100-300degreeC -- it is 150-250degreeC especially preferably. As the heat-resistant film 41, a fluorocarbon resin tube is used, for example and slitting about 3 mm in length may be formed in the axial end of a tube. It is for making the heat-resistant film 41 easy to remove after thermal melting arrival.

[0081]In the fuse section 44, after the distal end seal part 7 removes the metallic mold 43, removes the heat-resistant film 41 and removes the mandrel 40 after thermal melting arrival on the periphery of the inner tube 12, the garbage 7b by the side of the tip in the distal end seal part 7 is removed. Since the non-fused part 46 is formed in the distal end side of the fuse section 44 in the distal end seal part 7 when removing the garbage 7b, it is easily removable with a cutter etc. Then, the tip tapered surface 7a of the distal end seal part 7 is forced on the surface of revolution of the rotation disks for polish, for example, and polishing work is carried out so that the smooth tip taper part 7a may be formed. Then, as shown in drawing 5, the distal end of the inner tube 12 is

cut to the predetermined length Lf, chamfering work of the cutting plane is carried out, and the tapered surface 12c is formed.

[0082]Then, the distal end of the 2nd outer tube part 6b is joined to the proximal end part of the 1st outer tube member 6a. On the occasion of the junction, first, the tube for heat sealing is put on the periphery of the 2nd outer tube member 6b, and the distal end of the 2nd outer tube member 6b is stuffed into it in the lumen of the proximal end part of the 1st outer tube 6a. then, the 2nd outer tube member 6b — a mandrel is inserted in the inside of 24 along shaft orientations, and the 3rd lumen of the tip is made to project to the inside of the 1st outer tube member 6a. You make it located in the order or coincidence to lower [of the proximal edge opening 22 of the 2nd outer tube member 6b which inserts the 4th lumen of the reinforcing rod 28 in the inside of 26 along shaft orientations, and has formed the tip part in the periphery of the 1st outer tube member 6a].

[0083]Then, the tube for heat sealing is moved to shaft orientations, the joined part 9 of the 1st outer tube member 6a and the 2nd outer tube member 6b is covered by this tube for heat sealing, and thermal melting arrival is performed on the heat-sealing conditions mentioned above and the same heat-sealing conditions using a metallic mold.

[0084]Then, the tube for heat sealing is removed, and a mandrel is removed and the connector 8 shown in drawing 1 is joined to the proximal end part of the 2nd outer tube member 6b by thermal melting arrival or other means. Then, the covering material which comprises the hydrophilic polymer material which has lubricity in the peripheral face of the outer tube 6 by a damp or wet condition is covered if needed, and the balloon catheter 2 shown in drawing 1 is obtained.

[0085]Next, how to perform a PTCA therapy is explained using the balloon catheter 2 of the embodiment shown in drawing 1. First, the air in the balloon catheter 2 is removed as much as possible. Then, suction and injection means, such as a syringe, are attached to the port of the connector 8, fluids, such as a blood contrast medium (for example, iodine content), are put in in a syringe, suction and pouring are repeated, and the 3rd lumen of the air in 24, and 1st lumen 10 and the balloon part 4 is replaced by a fluid.

[0086]In order to insert the balloon catheter 2 into an arterial blood pipe, the guidewire for guide catheters (not shown) is first inserted into a blood vessel by Seldinger method etc. so that the tip may arrive to near the heart. Then, along with the guidewire for guide catheters, a guide catheter is inserted into an arterial blood pipe, and the tip is located in the coronary artery entrance of the heart which has a narrow segment. A narrow segment is formed, for example of a thrombus or arteriosclerosis.

[0087]Next, only the guidewire for guide catheters is sampled, the guidewire for balloon catheters thinner than it is inserted along with a guide catheter, and the tip is inserted to the position which passes a narrow segment.

[0088]Then, the distal end of a guidewire is inserted in the distance open end 20 of the balloon catheter 2 shown in drawing 1, and is pulled out from through and the proximal edge opening 22 in 1st lumen 14. And where the balloon part 4 is folded up, along with the guidewire 42, it lets the balloon catheter 2 pass in a guide catheter. And as shown in drawing 11, the balloon part 4 of the balloon catheter 2 is inserted to this side of the narrow segment 36 in the blood vessel 34.

[0089]Then, the balloon part 4 by which the balloon catheter 2 was folded up is inserted between narrow segments along with a guidewire. Next, the balloon part 4 is correctly located in the center section of the narrow segment, observing the position of the balloon part 4 with an X-ray fluoroscope etc. By swelling the balloon part 4 in the position, the narrow segment of a blood vessel can be extended and a good therapy can be performed. In order to swell the balloon part 4, the 3rd lumen is performed from the port of the connector 8 shown in drawing 1 24 and by letting 10 [lumen / 1st] pass and pouring in a fluid into the balloon part 4.

[0090]Although this expansion time in particular is not limited, it is a for [about 1 minute] grade, for example. Then, a fluid is promptly drained from the balloon part 4, a balloon part is shrunk, and the blood flow by the side of the tip of the extended narrow segment is secured. It is necessary to perform extension of a narrow segment gradually, it inserts the balloon catheter 2 which has the balloon part 4 of a small outer diameter at first along with a guidewire, and exchanges it for the balloon catheter 2 with the balloon part 4 of a big outer diameter one by one so that a blood vessel may not be damaged. The balloon catheter 2 applied to this embodiment in that case, Since it is a balloon catheter of a monorail method, clearing work of a balloon catheter can be performed only by extending the proximal end part of the guidewire 42 at the outside-of-the-body side to the grade slightly longer than the portion equivalent to the length of the inner tube 12.

[0091]In the balloon catheter 2 concerning this embodiment, the catheter tube structure of what is called coaxial structure which comprises the outer tube 6 and the inner tube 12 only in the distal end of the balloon catheter 2 is adopted, and the lumen 14 of the inner tube 12 is used as a lumen for guidewire insertion. For this reason, as compared with the conventional balloon catheter (JP,S63-288167,A and JP,H2-307479,A) which has the so-called catheter tube of a double lumen, it is easy to make thin the outer diameter of the 1st outer tube member 6a with the balloon catheter 2 concerning this embodiment. In the balloon catheter 2 concerning this

embodiment. The proximal edge opening 22 of the inner tube 12 used as the proximal edge side output port of a guidewire. The tube wall located in the middle of the longitudinal direction of the outer tube 6 is penetrated, and the opening is carried out outside, and in the opening 22, it becomes the dual structure of the inner tube 12 and the outer tube 6, and has structure which cannot carry out a kink easily.

[0092]In the balloon catheter 2 furthermore applied to this embodiment. The proximal edge opening 22 of the inner tube 12 used as the proximal edge side output port of the guidewire 42. It is not necessary to cover the overall length of the catheter tube 2 and to make a level difference, and the tube wall located in the middle of the longitudinal direction of the outer tube 6 is penetrated, and it is only carrying out the opening outside and excels in the insertion characteristic of the balloon catheter 2. Since it is the structure which cannot carry out a kink easily, it excels also in the pushing characteristic of the balloon catheter 2.

[0093]In this embodiment, as shown in drawing 2, since the reinforcing rod 28 is arranged from the opening 22 neighborhood inside the 1st outer tube member 6a by the side of a proximal edge, the pushing characteristic of a balloon catheter improves further, and. The distal end side of a catheter tube becomes flexible, and the insertion characteristic within the abdominal cavities, such as a blood vessel which wound, improves further.

[0094]Furthermore, by this embodiment, since the distal end 28a of the reinforcing rod 28 is not being fixed to the wall of the 1st outer tube member 6a. Even when a branching portion inserts the balloon catheter 2 in many [and] thin blood vessels like a coronary artery, the distal end of the 1st outer tube member 6a transforms it flexibly corresponding to the crooked part of a blood vessel. This is considered because it can change freely, without restricting the distal end of the 1st outer tube member 6a to the reinforcing rod 28, since the distal end 28a of the reinforcing rod 28 is not being fixed to the wall of the 1st outer tube member 6a.

[0095]By this embodiment, the proximal edge seal part 5 of the balloon part 4 has further again a part for the 1st non-connecting part 5b that does not overlap with the 1st joining section 5a joined to the distal end of the outer tube part 6 by overlapping. Although the amount of [in the proximal edge seal part 5 of the balloon part 4 / 5b] 1st non-connecting part is a portion which hardly contributes to the curative effect by extension of the balloon part 4, its pliability in the distal end of the balloon catheter 2 improves by providing the portion. The amount of [5b] 1st non-connecting part is a part of balloon part 4. It is because it is supply rather than the outer tube part 6.

[0096]Therefore, even when a branching portion inserts the balloon catheter 2 of this embodiment in many [and] thin blood vessels like a coronary artery, the distal end of the balloon catheter 2 transforms it flexibly corresponding to the crooked part of a blood vessel. That is, in the balloon catheter 2 of this embodiment, the insertion characteristic and the pushing characteristic of the balloon catheter 2 improve.

[0097]According to this embodiment, the tip taper part 7a to which an outer diameter becomes thin towards the distal end periphery of the inner tube 12 is formed in the distal end seal part 7 of the balloon part 4 joined to the distal end of the inner tube 12. And a part for the 2nd non-connecting part 12b to which the distal end seal part 7 of the balloon part 4 is not joined is formed in the distal end periphery of the inner tube 12.

[0098]For this reason, as shown in drawing 11, it is possible for the outer diameter of the distal end of the balloon catheter 2 to become equal to the outer diameter of the inner tube 12, and to insert the distal end of the balloon catheter 2 easily also to the narrow segment 36 of the blood vessel 34 which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of the balloon catheter 2 improves.

[0099]Especially, by this embodiment, since the diameter reduction part 58 which makes the diameter of the outer diameter of the inner tube 12 of the predetermined length range including the position equipped with the imaging ring 15 reduce compulsorily, and has an inside diameter of the imaging ring 15 and an outer diameter below equivalent is formed. The work which equips the diameter reduction part 58 of the inner tube 12 with the imaging ring 15 is easy. The outer diameter of the diameter reduction part 58 is restored to near the original outer diameter by equipping the diameter reduction part 58 with the imaging ring 15, and heating after that. Therefore, as shown in drawing 6, the imaging ring 15 serves as structure embedded on the periphery of the inner tube 12, and is fixed to the prescribed position.

[0100]Thus, the manufactured balloon catheter 2 serves as the structure where the imaging ring 15 is embedded on the periphery of the inner tube 12, and it is lost in the fixing point of the imaging ring 15 that the imaging ring 15 projects of it too much from the periphery of the inner tube 12. As a result, it is in the state which folded up the balloon part 4 on the periphery of the inner tube 12, and it is possible to become possible to make the outer diameter small, and to insert the distal end of the balloon catheter 2 easily also to the narrow segment of the blood vessel which wound when the grade of strangulation is intense especially. Therefore, the insertion characteristic of the balloon catheter 2 improves.

[0101]In the manufacturing method of the balloon catheter concerning this embodiment. boiling a balloon catheter comparatively -- 2 -- it can manufacture easily, and the bonding strength of the imaging ring 15 and

the inner tube 12 also comes out enough, and there is, and, moreover, it is hard to produce defects, like an inner tube becomes thin meat to a degree very much etc. on the occasion of the manufacture. On the occasion of junction to the imaging ring 15 and the inner tube 12, adhesives etc. are not necessarily needed.

[0102]this invention is not limited to the embodiment mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, in the embodiment mentioned above, although the outer tube 6 was constituted from the 1st outer tube member 6a and the 2nd outer tube member 6b, it is also possible to constitute the outer tube 6 from this invention by the single tube which follows shaft orientations. The use of the balloon catheter concerning this invention is not limited to the use mentioned above.

[0103]This invention can be applied not only to a balloon catheter but to the medical device in which the metal ring (it corresponds to the imaging ring 15 in the above-mentioned embodiment) used for the periphery of a tube as an electrode, a sensor, etc. is attached. As a medical device in which an electrode is attached to the periphery of a tube, an electrode catheter etc. are illustrated, for example.

[Translation done.]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]Drawing 1 is an entire configuration figure of the balloon catheter concerning one embodiment of this invention.

[Drawing 2]The sectional view which meets the IIB-IIB line shown in drawing 2 (A) drawing 1, the sectional view which meets the IIB-IIB line which shows drawing 1 drawing 2 (B), the sectional view which meets the IIC-IIC line which shows drawing 1 drawing 2 (C), and drawing 2 (D) are sectional views which meet the IID-IID line shown in drawing 1.

[Drawing 3]Drawing 3 is a side view of the reinforcing rod shown in drawing 1.

[Drawing 4]Drawing 4 is important section drawing of longitudinal section of the balloon catheter shown in drawing 1.

[Drawing 5]Drawing 5 is an important section sectional view showing the details of the distal end of the balloon catheter shown in drawing 4.

[Drawing 6]Drawing 6 is an important section sectional view showing the fitting structure of the imaging ring to the inner tube located in a balloon part.

[Drawing 7]Drawing 7 is an important section side view showing the mounting arrangement of the imaging ring to an inner tube.

[Drawing 8]Drawing 8 is an important section sectional view showing the composition of a continuation of drawing 7.

[Drawing 9]Drawing 9 is an important section sectional view showing the process of a continuation of drawing 8.

[Drawing 10]Drawing 10 is an important section sectional view showing the joining process of the distal end seal part of a balloon part, and the distal end of an inner tube.

[Drawing 11]Drawing 11 is an important section sectional view showing the example of use of the balloon catheter shown in drawing 1.

[Description of Notations]

2 -- Balloon catheter

4 -- Balloon part

4a -- Cylindrical section

4b, 4c -- Tapered shape reducing part

5 -- Proximal edge seal part

5a -- The 1st joining section

5b -- A part for the 1st non-connecting part

7 -- Distal end seal part

7a -- Tip taper part

7b -- Garbage

6 -- Outer tube

6a -- The 1st outer tube member

6b -- The 2nd outer tube member

8 -- Connector

10 -- The 1st lumen

12 -- Inner tube

12a -- The 2nd joining section

12b -- A part for the 2nd non-connecting part

14 -- The 2nd lumen

15 -- Imaging ring

20 -- Distal end opening

- 21 -- Breakthrough
- 22 -- Proximal edge opening
- 24 -- The 3rd lumen
- 26 -- The 4th lumen
- 28 -- Reinforcing rod
- 44 -- Fuse section
- 58 -- Diameter reduction part

[Translation done.]

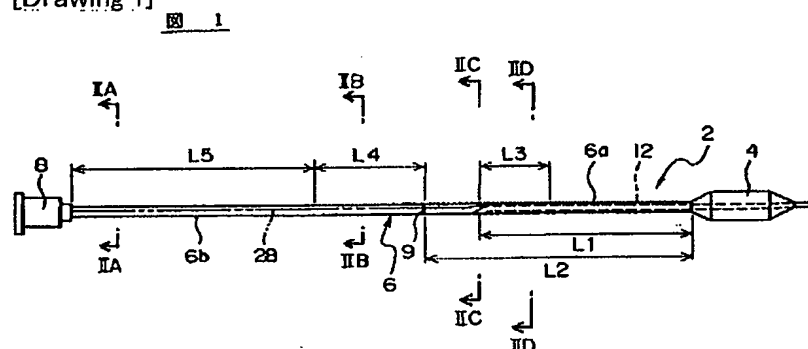
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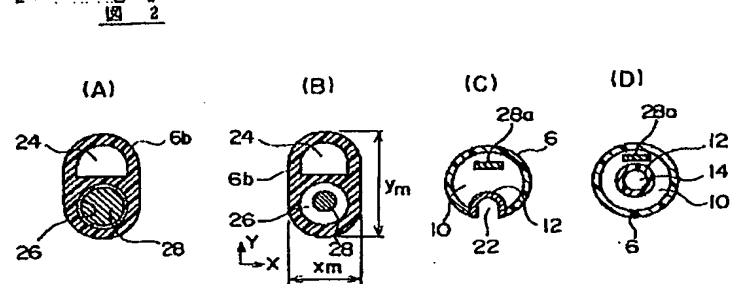
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DRAWINGS

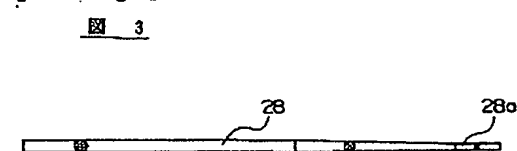
[Drawing 1]



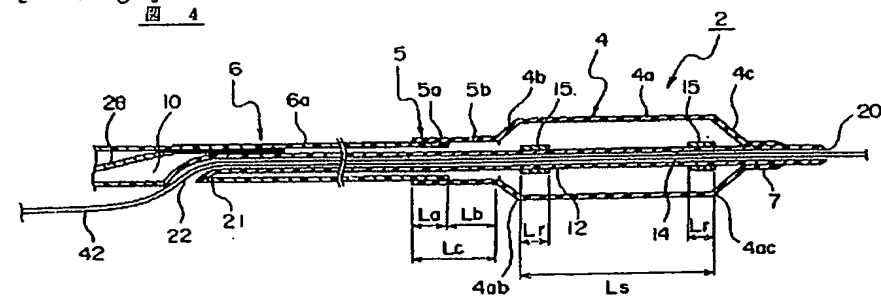
[Drawing 2]



[Drawing 3]

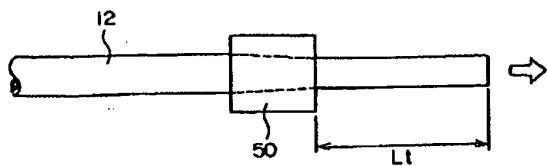


[Drawing 4]



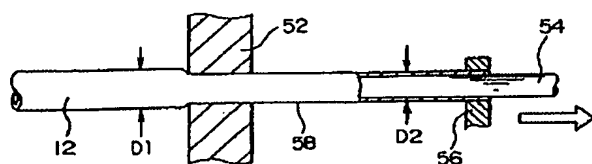
[Drawing 7]

図 7



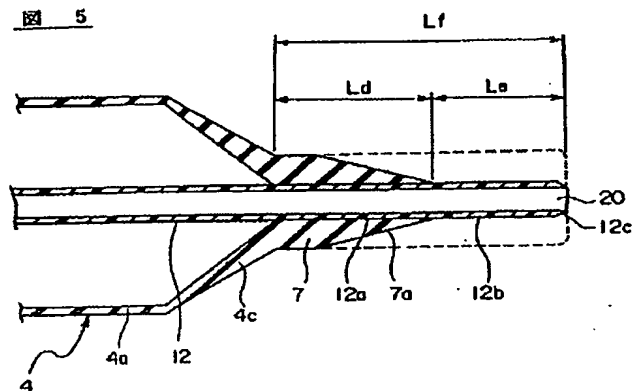
[Drawing 8]

図 8



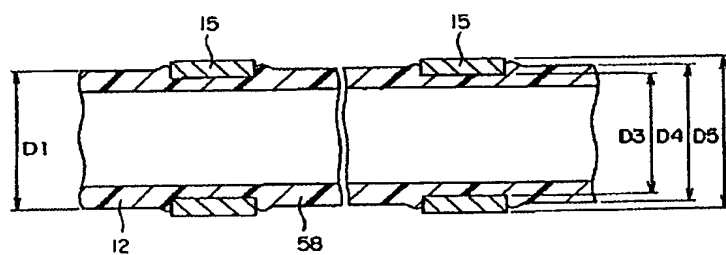
[Drawing 5]

図 5



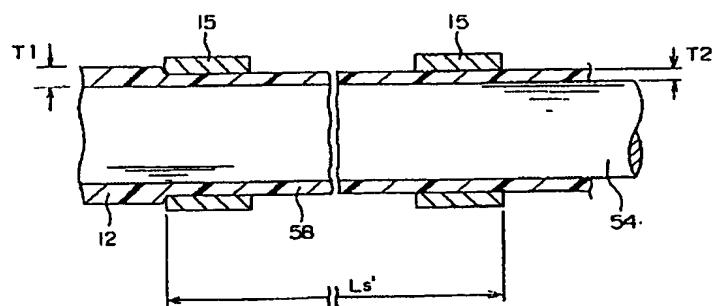
[Drawing 6]

図 6

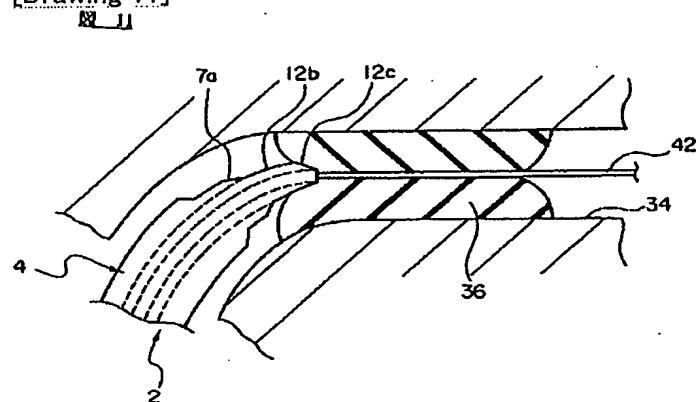


[Drawing 9]

図 9



10



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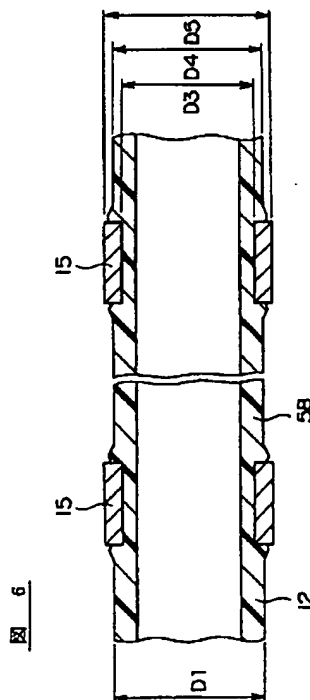
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(54) 【発明の名称】 医療器具およびその製造方法

(57) 【要約】

【課題】 金属リングが取り付けられるチューブ部分の外径を極力小さくでき、体腔内への挿入性に優れた医療器具と、その医療器具を、チューブに欠陥を生じさせることなく、きわめて容易に製造することができる医療器具の製造方法を提供すること。

【解決手段】 金属リング15が装着される位置を含む所定長さ範囲の合成樹脂チューブ12の外径を強制的に縮径させ、金属リング15の内径と同等以下の外径を持つ縮径部58を形成した後、縮径部58に金属リング15を装着し、その後、加熱することにより、縮径部58の外径を復元させ、金属リング15をチューブ12の所定位置に固定する。



【特許請求の範囲】

【請求項1】 金属リングが装着される位置を含む所定長さ範囲の合成樹脂チューブの外径を強制的に縮径させ、前記金属リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に金属リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記金属リングを前記チューブの所定位置に固定してあることを特徴とする医療器具。

【請求項2】 前記金属リングの外径に対する復元後の前記チューブの外径の比が、0.7～1であることを特徴とする請求項1に記載の医療器具。

【請求項3】 前記金属リングの内径に対する復元後の前記チューブの外径の比が、1～1.2であることを特徴とする請求項1または2に記載の医療器具。

【請求項4】 少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近位端封止部分が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端封止部分が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブと、前記バルーン部の内部に位置する前記内チューブの外周部に装着された少なくとも1つの造影リングと、を有するバルーンカテーテルであって、前記造影リングが装着される位置を含む所定長さ範囲の内チューブの外径を強制的に縮径させ、前記造影リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に造影リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記造影リングを前記内チューブの所定位置に固定することを特徴とするバルーンカテーテル。

【請求項5】 前記造影リングの外径に対する復元後の前記内チューブの外径の比が、0.7～1であることを特徴とする請求項4に記載のバルーンカテーテル。

【請求項6】 前記造影リングの内径に対する復元後の前記内チューブの外径の比が、1～1.2であることを特徴とする請求項4または5に記載のバルーンカテーテル。

【請求項7】 金属リングが装着される位置を含む所定長さ範囲の合成樹脂チューブの外径を強制的に縮径させ、前記金属リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に金属リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記金属リングを前記チューブの所定位置に固定することを特徴とする医療器具の製造方法。

【請求項8】 前記縮径部の加熱温度は、前記チューブを構成する合成樹脂の融点から5～20℃程度低温側の

範囲にあることを特徴とする請求項7に記載の医療器具の製造方法。

【請求項9】 前記縮径部は、前記チューブの遠位端部を軸方向に引っ張ることにより形成されることを特徴とする請求項7または8に記載の医療器具の製造方法。

【請求項10】 前記チューブのルーメン内部にマンドレルが挿入された状態で、前記縮径部が形成されることを特徴とする請求項7～9のいずれかに記載の医療器具の製造方法。

【請求項11】 少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近位端封止部分が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端封止部分が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブと、前記バルーン部の内部に位置する前記内チューブの外周部に装着された少なくとも1つの造影リングと、を有するバルーンカテーテルの製造方法であって、前記造影リングが装着される位置を含む所定長さ範囲の内チューブの外径を強制的に縮径させ、前記造影リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に少なくとも一つの造影リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記造影リングを前記内チューブの所定位置に固定することを特徴とするバルーンカテーテルの製造方法。

【請求項12】 前記縮径部の加熱温度は、前記内チューブを構成する合成樹脂の融点から5～20℃程度低温側の範囲にあることを特徴とする請求項11に記載のバルーンカテーテルの製造方法。

【請求項13】 前記縮径部は、前記内チューブの遠位端部を軸方向に引っ張ることにより形成されることを特徴とする請求項11または12に記載のバルーンカテーテルの製造方法。

【請求項14】 前記内チューブのルーメン内部にマンドレルが挿入された状態で、前記縮径部が形成されることを特徴とする請求項11～13のいずれかに記載のバルーンカテーテルの製造方法。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、バルーンカテーテルなどの医療器具とその製造方法に係り、さらに詳しくは、電極やセンサなどとして用いられる金属リングが取り付けられる医療器具、またはX線造影のための造影リングが取り付けられる医療器具と、その製造方法に関する。

【0002】

【従来の技術】近年、医療技術は、低侵襲治療に向かう傾向にある。たとえば冠状動脈の狭窄は、以前の冠状動脈バイパス手術に代わって、血管拡張用バルーンカテーテルによって処置されることが多くなってきている。この治療方法は、経済的な利点と共に、患者の負担を大きく軽減するために、ますます適用範囲を拡大している。それと共に、さらに高効率で簡単な冠状動脈の狭窄拡張に用いるバルーンカテーテルの構造が求められている。

【0003】血管内の狭窄部を治療するために、血管内に挿入し、バルーン部を膨らますことにより狭窄部を拡張し、狭窄部末梢側における血流の改善を図るための、いわゆるPTCAバルーンカテーテルとして、オーバー・ザ・ワイヤ方式のバルーンカテーテルとモノレール方式のバルーンカテーテル（たとえば特開2000-217923号公報）とがある。これらの方式のバルーンカテーテルでは、いずれも、先にガイドワイヤを血管内狭窄部へ通過させておき、次にこのガイドワイヤに沿ってバルーンカテーテルを狭窄部まで送り込み、バルーン部を膨らますことにより狭窄部を拡張する。

【0004】このようなPTCAバルーンカテーテルを初めとして、従来のバルーンカテーテルにおいては、カテーテルチューブを構成する外チューブの内部に内チューブが配置されるものが多い。内チューブのルーメンは、ガイドワイヤ挿通孔として用いられ、内チューブの遠位端部の外周に、バルーン部の遠位端部が熱融着され、バルーン部の内部を密封している。

【0005】従来のバルーンカテーテルにおいては、血管内に挿入されたPTCAバルーンカテーテルの位置を把握するために、バルーン部の内部に位置する内チューブの外周には、タングステンなどで構成された造影リングが取り付けられている。一般に、造影リングは、内チューブの外側から嵌め込まれるために、その部分の外径は、内チューブの外径よりも大きくなり、内チューブの形状が極端に凸になる。このために、バルーン部を折り畳んだ状態のバルーンカテーテルを血管の狭窄部分へ通過させようとする場合に障害となることが考えられる。

【0006】なお、特開平8-289934号公報に示すように、内チューブの所定位置にエッチングなどの加工手段により凹溝を設け、その凹溝に造影リングを取り付けた構造が提案されている。しかしながら、この構造のバルーンカテーテルでは、きわめて薄肉の内チューブの外周に凹溝を形成する際に、内チューブの肉厚が薄くなりすぎて、内チューブに欠陥が生じやすい。また、内チューブに凹溝を加工した後に、その凹溝に造影リングを取り付けることが困難である。

【0007】また、バルーンカテーテル以外の医療器具においては、造影リングなどの用途以外に、電極やセンサなどとして用いられる金属リングが合成樹脂製チューブの外周に取り付けられる医療器具があり、この場合にも、バルーンカテーテルと同様な不都合を有している。

【0008】

【発明が解決しようとする課題】本発明は、このような実情に鑑みて成され、本発明の目的は、金属リングが取り付けられるチューブ部分の外径を極力小さくでき、体腔内への挿入性に優れた医療器具と、その医療器具を、チューブに欠陥を生じさせることなく、きわめて容易に製造することができる医療器具の製造方法を提供することである。

【0009】また、本発明の第2の目的は、特に狭窄の程度が激しい場合や、曲がりくねった血管の狭窄部に対しても、バルーンカテーテルの遠位端を、容易に挿入することが可能であり、挿入特性に優れたバルーンカテーテルと、そのバルーンカテーテルを、内チューブに欠陥を生じさせることなく、きわめて容易に製造することができるバルーンカテーテルの製造方法とを提供することである。

【0010】

【課題を解決するための手段】上記第1の目的を達成するために、本発明に係る医療器具は、金属リングが装着される位置を含む所定長さ範囲の合成樹脂チューブの外径を強制的に縮径させ、前記金属リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に金属リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記金属リングを前記チューブの所定位置に固定してあることを特徴とする。

【0011】好ましくは、前記金属リングの外径に対する復元後の前記チューブの外径の比が、0.7～1である。

【0012】好ましくは、前記金属リングの内径に対する復元後の前記チューブの外径の比が、1～1.2である。

【0013】本発明に係る医療器具の製造方法は、金属リングが装着される位置を含む所定長さ範囲の合成樹脂チューブの外径を強制的に縮径させ、前記金属リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に金属リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記金属リングを前記チューブの所定位置に固定することを特徴とする。

【0014】好ましくは、前記縮径部の加熱温度は、前記チューブを構成する合成樹脂の融点から5～20℃程度低温側の範囲にある。

【0015】好ましくは、前記縮径部は、前記チューブの遠位端部を軸方向に引っ張ることにより形成される。

【0016】好ましくは、前記チューブのルーメン内部にマンドレルが挿入された状態で、前記縮径部が形成される。

【0017】上記第2の目的を達成するために、本発明に係るバルーンカテーテルは、少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近

位端封止部分が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端封止部分が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブと、前記バルーン部の内部に位置する前記内チューブの外周部に装着された少なくとも1つの造影リングと、を有するバルーンカテーテルであって、前記造影リングが装着される位置を含む所定長さ範囲の内チューブの外径を強制的に縮径させ、前記造影リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に造影リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記造影リングを前記内チューブの所定位置に固定することを特徴とする。

【0018】好ましくは、前記造影リングの外径に対する復元後の前記内チューブの外径の比が、0.7～1である。

【0019】好ましくは、前記造影リングの内径に対する復元後の前記内チューブの外径の比が、1～1.2である。

【0020】本発明に係るバルーンカテーテルの製造方法は、少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近位端封止部分が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端封止部分が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブと、前記バルーン部の内部に位置する前記内チューブの外周部に装着された少なくとも1つの造影リングと、を有するバルーンカテーテルの製造方法であって、前記造影リングが装着される位置を含む所定長さ範囲の内チューブの外径を強制的に縮径させ、前記造影リングの内径と同等以下の外径を持つ縮径部を形成した後、前記縮径部に少なくとも一つの造影リングを装着し、その後、加熱することにより、前記縮径部の外径を復元させ、前記造影リングを前記内チューブの所定位置に固定することを特徴とする。

【0021】好ましくは、前記縮径部の加熱温度は、前記内チューブを構成する合成樹脂の融点から5～20℃程度低温側の範囲にある。

【0022】好ましくは、前記縮径部は、前記内チューブの遠位端部を軸方向に引っ張ることにより形成される。

【0023】好ましくは、前記内チューブのルーメン内部にマンドレルが挿入された状態で、前記縮径部が形成される。

【0024】

【作用】本発明に係る医療器具の製造方法では、金属リングが装着される位置を含む所定長さ範囲の合成樹脂チューブの外径を強制的に縮径させ、金属リングの内径と同等以下の外径を持つ縮径部を形成するので、チューブの縮径部に金属リングを装着する作業が容易である。その縮径部に金属リングを装着し、その後、加熱することにより、前記縮径部の外径は、元の外径近くまで復元する。したがって、金属リングは、内チューブの外周に埋め込まれる構造となり、その所定位置に固定される。

【0025】このようにして製造された医療器具は、金属リングが内チューブの外周に埋め込まれる構造となり、その金属リングの装着位置において、金属リングがチューブの外周から過度に突出することが無くなる。その結果、金属リングが装着される部分の外径を小さくすることが可能になり、医療器具の挿入特性が向上する。

【0026】また、本発明に係る医療器具の製造方法では、本発明に係る医療器具を、比較的容易に製造することができ、金属リングとチューブとの接合強度も十分であり、しかも、その製造に際し、チューブが極度に薄肉になるなどの欠陥などが生じにくい。また、金属リングとチューブとの接合に際し、必ずしも接着剤などを必要としない。

【0027】本発明に係るバルーンカテーテルの製造方法では、造影リングが装着される位置を含む所定長さ範囲の内チューブの外径を強制的に縮径させ、前記造影リングの内径と同等以下の外径を持つ縮径部を形成するので、内チューブの縮径部に造影リングを装着する作業が容易である。その縮径部に造影リングを装着し、その後、加熱することにより、前記縮径部の外径は、元の外径近くまで復元する。したがって、造影リングは、内チューブの外周に埋め込まれる構造となり、その所定位置に固定される。

【0028】このようにして製造されたバルーンカテーテルは、造影リングが内チューブの外周に埋め込まれる構造となり、その造影リングの装着位置において、造影リングが内チューブの外周から過度に突出することが無くなる。その結果、バルーン部を内チューブの外周に折り畳んだ状態で、その外径を小さくすることが可能になり、特に狭窄の程度が激しい場合や、曲がりくねった血管の狭窄部に対しても、バルーンカテーテルの遠位端を、容易に挿入することが可能である。したがって、バルーンカテーテルの挿入特性が向上する。

【0029】また、本発明に係るバルーンカテーテルの製造方法では、本発明に係るバルーンカテーテルを、比較的容易に製造することができ、造影リングと内チューブとの接合強度も十分であり、しかも、その製造に際し、内チューブが極度に薄肉になるなどの欠陥などが生じにくい。また、造影リングと内チューブとの接合に際し、必ずしも接着剤などを必要としない。

【0030】

【発明の実施の形態】以下、本発明を、図面に示す実施形態に基づき説明する。図1に示す本実施形態に係るバルーンカテーテル2は、たとえば経皮的冠動脈形成術(PTCA)、四肢等の血管の拡張術、上部尿管の拡張術、腎血管拡張術などの方法に用いられ、血管あるいはその他の体腔に形成された狭窄部を拡張するために用いられる。以下の説明では、本実施形態のバルーンカテーテル2をPTCAに用いる場合を例として説明する。

【0031】本実施形態の拡張用バルーンカテーテル2は、いわゆるモノレール方式のバルーンカテーテルであり、バルーン部4と、カテーテルチューブとしての外チューブ6と、内チューブ12と、コネクタ8とを有する。

【0032】図1および図4に示すバルーン部4は、膨らんだ状態で外チューブ6の外径よりも大きな外径を持つ筒状部分4aを有する。筒状部分4aの両端部には、それに連続するテーパ状縮径部分4bおよび4cと、それらにそれぞれ連続する近位端封止部分5および遠位端封止部分7とが一体に成形してある。近位端封止部分5は、外チューブ6の遠位端外周部分に接続されるように、筒状部分4aよりも小さな外径を有する。また、遠位端封止部分7は、内チューブ12の遠位端外周部分に接続されるように、近位端封止部分5よりも小さな外径を有する。

【0033】バルーン部4の膜厚は、特に限定されないが、15~300 μ m、好ましくは30~150 μ mである。バルーン部4の筒状部分4aは、筒状であれば、特に限定されず、円筒または多角筒形状でも良い。また、拡張時のバルーン部4の外径は、血管の内径などの因子によって決定され、通常1.5~10.0mm程度、好ましくは、3~7mmである。このバルーン部4における筒状部分4aの軸方向長さは、血管内狭窄部の大きさなどの因子によって決定され、特に限定されないが、15~50mm、好ましくは20~40mmである。拡張する前のバルーン部4は、内チューブ12の周囲に折り畳まれて巻き付けられ、可能な限り外径が小さくなっている。

【0034】バルーン部4を構成する材質は、ある程度の可撓性を有する材質であることが好ましく、たとえばポリエチレン、ポリエチレンテレフタレート、ポリプロピレン、エチレン-プロピレン共重合体等のエチレンと他の α -オレフィンとの共重合体、エチレン-酢酸ビニル共重合体、ポリ塩化ビニル(PVC)、架橋型エチレン-酢酸ビニル共重合体、ポリウレタン、ポリアミド、ポリアミドエラストマー、ポリイミド、ポリイミドエラストマー、シリコーンゴム、天然ゴムなどが使用でき、好ましくは、ポリエチレン、ポリエチレンテレフタレート、ポリアミドである。バルーン部4は、内部に流体が導入されることにより、膨らんだり萎んだりできるように、チューブ6および12よりも柔軟な材質および厚み

で構成される。

【0035】図4に示すように、バルーン部4の近位端封止部分5は、外チューブ6の遠位端部に重複して接合される第1接合部分5aと、この第1接合部分5aと略同じ外径を持ち外チューブ6の遠位端部に重複していない第1非接合部分5bとを有する。第1接合部分5aは、外チューブ6の遠位端部外周に、熱融着または接着などの手段で接合してあり、外チューブ6の第1ルーメン10がバルーン部4の内部拡張用空間と連通するようになっている。バルーン部4の遠位端封止部分7は、内チューブ12の遠位端部外周に対して熱融着または接着などの手段で接合してあり、バルーン部4の内部拡張用空間は、第1ルーメン10以外では、外部に対して密封してある。外チューブ6の第1ルーメン10は、バルーン部4の内部拡張空間に流体を送り込み、バルーン部4を拡張させたり、流体をバルーン部4の拡張空間から抜き取りバルーン部4を収縮させたりするための通路である。

【0036】本実施形態では、バルーン部4の近位端封止部分5において、第1接合部分5aの軸方向長さ L_a と、第1非接合部分5bの軸方向長さ L_b との比($L_a:L_b$)が、1:1~1:10、さらに好ましくは、1:2~1:5の範囲にある。第1接合部分5aの軸方向長さ L_a は、好ましくは2~5mmである。また、第1非接合部分5bの軸方向長さ L_b は、好ましくは15~20mmである。第1接合部分5aの軸方向長さ L_a が短すぎると、接合が不十分になる傾向にあり、長すぎると、重複部分の長さが長くなり、その部分での柔軟性が低下する傾向にある。また、第1非接合部分5bの軸方向長さ L_b が短すぎると、従来のバルーンカテーテルと同様な不都合を有する傾向にあり、長すぎると、バルーン部4の強度が低下する傾向にある。なお、近位端封止部分5の全長 L_c は、好ましくは17~25mmである。

【0037】図4に示すように、内チューブ12は、バルーン部4の拡張空間および外チューブ6の遠位端側第1ルーメン10の内部を同軸状に軸方向に伸び、いわゆる同軸構造のカテーテルチューブ構造となっている。バルーン部4の内部に位置する内チューブ12の外周には、一対の造影リング15が装着してあり、バルーンカテーテル2を生体内に挿入する際に、生体の外部からX線などで造影リング15の位置を造影が可能になっている。造影リング15の材質としては、金、白金、タングステンなどの金属が例示される。

【0038】それぞれの造影リング15の軸方向長さ L_r は、好ましくは0.5~2mm、さらに好ましくは、1~1.2mmである。バルーンカテーテル2の遠位端側に配置される造影リング15の遠位端は、バルーン部4における筒状部分4aとテーパ状縮径部分4cとの交差部4acに対応する位置に位置する。また、バルーンカテーテル2の近位端側に配置される造影リング15の近位

端は、バルーン部4における筒状部分4aとテーパ状縮径部分4bとの交差部4abに対応する位置に位置する。

【0039】すなわち、遠位端側の造影リング15の遠位端から近位端側の造影リング15の近位端までの距離Lsは、筒状部分4aの長さに対応する。したがって、一对の造影リング15の位置をX線などで検出することにより、バルーン部4における筒状部分4aの位置を正確に把握することができる。この筒状部分4aが、血管などに生じた狭窄部の拡張に寄与する部分である。これらの造影リング15は、図6に示すように、内チューブ12の外周に埋め込まれて固定されている。その埋め込み固定方法については、後述する。

【0040】図5に示すように、バルーン部4の遠位端封止部分7の先端部には、内チューブ12の遠位端外周に向けて外径が細くなる先端テーパ部7aが形成してある。また、その先端テーパ部7aのさらに遠位端側には、内チューブ12の遠位端部が軸方向に突出しており、その結果、内チューブ12の遠位端部外周には、バルーン部4の遠位端封止部分7が接合される第2接合部12aと、接合されていない第2非接合部分12bとが形成してある。

【0041】本実施形態では、バルーン部4の遠位端封止部分7において、第2接合部分12aの軸方向長さLdと、第2非接合部分12bの軸方向長さLeとの比(Ld:Le)が、1:2~4:1、さらに好ましくは、1.5:1~3:1の範囲にある。第2接合部分12aの軸方向長さLdは、好ましくは1.5~3mmである。また、第2非接合部分12bの軸方向長さLeは、好ましくは0.5~1.5mmである。第2接合部分12aの軸方向長さLdが短すぎると、接合が不十分になる傾向にあり、長すぎると、接合部分の長さが長くなり、その部分での柔軟性が低下する傾向にある。また、第2非接合部分12bの軸方向長さLeが短すぎると、従来のバルーンカテーテルと同様な不都合を有する傾向にあり、長すぎると、材料の無駄であると共に、治療の邪魔になる傾向にある。なお、第2接合部分12aと第2非接合部分12bとの合計長さLfは、好ましくは3.5~5.5mmである。なお、本実施形態では、内チューブ12の遠位端外周にも、先細となるテーパ部12cが形成してある。

【0042】内チューブ12の内部には、第2ルーメン14が形成してあり、その遠位端開口部20は、バルーン部4の遠位端封止部分7よりも遠位端側で開口している。内チューブ12の近位端開口部22は、図1および図2に示すように、外チューブ6の長手方向の途中に位置するチューブ壁の貫通孔21を貫通して外部に開口している。内チューブ12の近位端開口部22の周縁と、外チューブ6のチューブ壁の貫通孔21の周縁とは、熱融着方法により気密に接合してある。内チューブ12の

近位端開口部22の形状は、特に限定されず、円形、楕円形など種々の形状を採り得るが、本実施形態では、内チューブ12の開口端部を斜めに切断した楕円形状である。内チューブ12の第2ルーメン14は、バルーンカテーテル2を体腔内に案内するための図4に示すガイドワイヤ42が挿通するガイドワイヤ挿入用ルーメンとなる。ガイドワイヤ42は、たとえばステンレス鋼、銅、銅合金、チタン、チタン合金などの単線または撚り線で構成してあり、その外径は、特に限定されないが、好ましくは、0.1~1mm、さらに好ましくは0.25~0.6mmである。

【0043】本実施形態では、外チューブ6は、円形断面の第1外チューブ部材6aと、当該第1外チューブ部材6aの近位端部に接合された異形断面の第2外チューブ部材6bとを有し、内チューブ12の近位端開口部22が、第1外チューブ部材6aの長手方向の途中に位置するチューブ壁を貫通して外部に開口している。第1外チューブ6aの軸方向長さL2は、特に限定されないが、好ましくは100~400mm、さらに好ましくは200~300mmである。

【0044】第1外チューブ部材6aは、たとえばバルーン部4と同様な材質で構成されて良いが、可撓性を有する材質で構成されることが好ましく、たとえばポリエチレン、ポリエチレンテレフタレート、ポリプロピレン、エチレン-プロピレン共重合体、エチレン-酢酸ビニル共重合体、ポリ塩化ビニル(PVC)、架橋型エチレン-酢酸ビニル共重合体、ポリウレタン、ポリアミド、ポリアミドエラストマー、ポリイミド、ポリイミドエラストマー、シリコンゴム、天然ゴムなどが使用でき、好ましくは、ポリエチレン、ポリアミド、ポリイミドで構成される。

【0045】第1外チューブ部材6aを構成する軟質の合成樹脂としては、好ましくはポリウレタン、ポリアミド、ポリイミド、ポリエチレンなどのJIS硬度が50A~90A程度のものを用いることができる。

【0046】内チューブ12は、第1外チューブ6aと同様な材質の軟質合成樹脂で構成することができるが、第1外チューブ6aよりも硬質の合成樹脂で構成しても良い。内チューブ12の近位端開口部22が第1外チューブ部材6aの外側に開口する位置は、第1外チューブ部材6aの遠位端から長さL1の位置であることが好ましく、長さL1は、好ましくは150~350mm、さらに好ましくは200~300mmである。また、第1外チューブ部材6aの外径は、特に限定されないが、好ましくは0.5~5mm、さらに好ましくは0.5~1mmである。第1外チューブ部材6aの肉厚は、特に限定されないが、好ましくは0.05~0.5mm、さらに好ましくは0.1~0.2mmである。

【0047】内チューブ12の外径は、第1外チューブ部材6aとの間に隙間が形成されるように決定され、特

に限定されないが、好ましくは0.3～3mm、さらに好ましくは0.3～0.8mmである。内チューブ12の内径は、ガイドワイヤ42を挿通できる径であれば特に限定されず、たとえば0.15～1.0mm、好ましくは0.25～0.6mmである。

【0048】第2外チューブ部材6bは、第1外チューブ部材6aと同じ材質で構成しても良いが、他の材質で構成することが好ましい。たとえば第1外チューブ部材6aを、第2外チューブ部材6bよりも軟質の合成樹脂で構成することが好ましい。

【0049】第1外チューブ部材6aを構成する軟質の合成樹脂としては、好ましくはポリウレタン、ポリアミド、ポリイミド、ポリエチレンなどのJIS硬度が50A～90A程度のもので用いることができ、第2外チューブ部材6bを構成する硬質の合成樹脂としては、ポリウレタン、ポリアミド、ポリイミド、ポリエチレンなどのJIS硬度が50D～75Dのもので用いることができる。

【0050】本実施形態では、図2(B)に示すように、第2外チューブ部材6bの横断面外形形状は、Y軸方向に細長い楕円形状を有し、外チューブ部材6bの断面で、Y軸と垂直なX軸方向のカテーテルチューブの最大断面幅xmと、Y軸方向の最大断面幅ymとの比(xm/ym)が、0.8～0.1の範囲にあり、断面半円形の第3ルーメン24および断面円形の第4ルーメン26が、前記Y軸方向に沿って分離して形成してある。

【0051】第3ルーメン24の半円形の横断面積は、バルーン拡張用圧力流体が流通するために十分な横断面積であれば良く、特に限定されないが、好ましくは0.08～0.20mm²である。また、第4ルーメン26の円形の横断面積は、内部に補強ロッド28が挿入されるために十分な面積であれば良く、特に限定されないが、好ましくは0.05～0.5mm²、さらに好ましくは0.1～0.2mm²である。

【0052】本実施形態では、第2外チューブ部材6bの断面において、Y軸方向の最大断面幅ymは、0.6～1.2mm程度が好ましい。第2外チューブ部材6bの遠位端は、断面円形の第1外チューブ部材6aの近位端に対して接合されるため、その接合部9付近の横断面形状は、第1外チューブ部材6aとの円形断面形状と一致させるために、接合部9に向けて、異形断面から円形断面に徐々に変化するような断面形状とする。

【0053】この第2外チューブ部材6bの長手方向に沿って形成された第3ルーメン24は、第1外チューブ部材6aの第1ルーメン10と連通し、これらを通して、バルーン部4の拡張用空間に流体の出し入れを行う。第2外チューブ部材6bの第4ルーメン26は、補強ロッド28を挿入するためのルーメンであり、第1外チューブ部材6aの第1ルーメン10とも連通するが、このルーメン26の近位端は、コネクタ8の部分で閉じられ

ており、流体の出入りは行わない。コネクタ8には、第2外チューブ部材6bの近位端部が連結され、第2外チューブ部材6bの第3ルーメン24に対して連通するポートが形成してある。そのポートは、圧力流体の出入りを行う部分であり、第4ルーメン26には、連通しないようになっている。

【0054】図1、図2(A)～図2(C)および図3に示す補強ロッド28は、第2外チューブ部材6bの第4ルーメン26の内部に、全長に亘り挿入され、その遠位端部は、第1外チューブ部材6aとの接合部9を乗り越えて、第1外チューブ部材6aの第1ルーメン10内に飛び出している。補強ロッド28の近位端部は、断面円形であり、途中から遠位端側に向けてテーパ状に細くなり、さらに遠位端部では、断面平板形状に成るようになり、その断面形状が徐々に変化している。断面平板状の補強ロッド28の遠位端部28aは、図1および図4に示すように、内チューブ12の近位端開口部22をも僅かに(好ましくはL3=1～10cm程度)乗り越えた位置まで延在し、その遠位端部28aは、第1外チューブ部材6aの内壁に対して固定されていない。

【0055】本実施形態では、補強ロッド28の近位端部は、第2外チューブ部材6bの第4ルーメン26の内部に、全長に亘り挿入され、その近位端から所定長さL5の範囲において、接着剤により第4ルーメン26の内壁に固定されている。すなわち、本実施形態では、チューブ接合部9から所定長さL4の位置から遠位端側では、補強ロッド28は、第4ルーメン26の内壁に固定されていないと共に、第1外チューブ部材6aの第1ルーメン10の内壁にも固定されていない。所定長さL4およびL5は、特に限定されないが、好ましくはL4=50～150mmであり、好ましくはL5=1000～15000mmである。

【0056】なお、補強ロッド28の最大外径は、第2外チューブ部材6bの第4ルーメン26の内部に挿入可能に決定され、特に限定されないが、好ましくは0.3～0.6mmである。補強ロッド28は、ステンレス鋼、銅、銅合金、チタン、チタン合金などの金属材料、あるいはポリイミド、ポリアミド、ポリエチレンテレフタレートなどの合成樹脂で構成してある。

【0057】コネクタ8のポートを通して第1ルーメン10内に導入される圧力流体としては、特に限定されないが、たとえば放射線不透過性媒体と生理食塩水との50/50混合水溶液などが用いられる。放射線不透過性媒体を含ませるのは、バルーンカテーテル2の使用時に、放射線を用いてバルーン部4および外チューブ6の位置を造影するためである。バルーン部4を膨らますための圧力流体の圧力は、特に限定されないが、絶対圧で3～12気圧、好ましくは、4～18気圧程度である。

【0058】本実施形態では、第1外チューブ部材6aと第2外チューブ部材6bとから成る外チューブ6の外

周には、湿潤状態で潤滑性を持つ親水性高分子物質から成る被覆材が被覆してあることが好ましい。このような被覆材で外チューブ6の外周を被覆することで、バルーンカテーテル2を血管などに挿入する際の挿入抵抗の低減を図ることができる。バルーン4の外周も被覆材で被覆しても良いが、バルーン部4は、血管などの狭窄部を拡張するものであり、狭窄部を拡張する際に、狭窄部に対してバルーン部が滑ることは必ずしも好ましくはない。そこで、本実施形態では、外チューブ6の外周のみを、親水性高分子物質から成る被覆材で被覆してある。

【0059】親水性高分子物質としては、天然高分子系のものと、合成高分子系のものとがある。天然高分子系のものとしては、デンプン系、セルロース系、タンニン・ニグニン系、多糖類系、タンパク質系などが例示される。合成高分子系のものとしては、PVA系、ポリエチレンオキシド系、アクリル酸系、無水マレイン酸系、フタル酸系、水溶性ポリエステル、ケトンアルデヒド樹脂、(メタ)アクリルアミド系、ビニル異節環系、ポリアミン系、ポリ電解質、水溶性ナイロン系、アクリル酸グリシジルアクリレート系などが例示される。

【0060】これらの中でも、外チューブ6の被覆材として好適に用いることができる親水性高分子物質としては、特に、セルロース系高分子物質(たとえばヒドロキシプロピルセルロース)、ポリエチレンオキシド系高分子物質(たとえばポリエチレングリコール)、無水マレイン酸系高分子物質(たとえばメチルビニルエーテル無水マレイン酸共重合体のような無水マレイン酸共重合体)、アクリルアミド系高分子物質(たとえばポリジメチルアクリルアミド)、水溶性ナイロン(たとえば東レ社製のAQ-ナイロン P-70)またはそれらの誘導体は、低い摩擦係数が安定して得られるので好ましい。

【0061】次に、本実施形態に係るバルーンカテーテル2の製造方法について説明する。まず、図4に示すバルーン部4を形成する。バルーン部4は、バルーン膜成形用マンドレルを溶液に浸して成形するディッピング法により成形しても良いし、ブロー成形により成形しても良い。

【0062】ディッピング法に用いられる溶液中の熱可塑性樹脂としては、特に限定されないが、たとえば、塩化ビニル系樹脂、ウレタン系樹脂、アミド系樹脂、オレフィン系樹脂、イミド系樹脂などを例示することができる。その中でも、耐屈曲疲労特性に優れたウレタン系樹脂が好ましい。

【0063】熱可塑性樹脂を可塑化させる溶媒としては、塩化ビニル系樹脂に対しては、テトラヒドロフラン(THF)、メチルエチルケトン(MEK)などが適当であり、ウレタン系樹脂に対しては、THF、MEK、ジメチルアセトアミド、ジメチルスルフォキシドなどが適当である。熱可塑性樹脂の溶液溶媒は、上記熱可塑性樹脂を溶媒により溶解した溶液であり、たとえば熱可塑

性樹脂としてポリウレタンを用い、溶媒としてTHFを用いる場合には、ポリウレタンが5~20重量%含まれる溶液を用いることが好ましい。この溶媒溶液の粘度は、100~10000cP、好ましくは1000~5000cPに予め調整される。このようにして成形されたバルーン部4の遠位端には、図4に示すように、先細と成るテーパ状縮径部分4cおよび遠位端封止部分7が一体に成形され、バルーン部4の近位端には、図4に示すように、先細と成るテーパ状縮径部分4bおよび近位端封止部分5が一体に成形される。

【0064】次に、バルーン部4の近位端封止部分5における第1接合部分5aを第1外チューブ部材6aの遠位端部外周に接合する。その接合に際しては、第1外チューブ部材6aの遠位端部内にマンドレルを挿入し、その後、部材6aの遠位端部の外周に、バルーン部4の近位端封止部分5における第1接合部分5aを重複させる。そして、第1接合部分5aの外周を耐熱性フィルムで覆い、その耐熱性フィルムを、金型などで加熱することにより、第1接合部分5aを第1外チューブ部材6aの遠位端部に熱融着させる。加熱温度は、特に限定されないが、好ましくは100~300°C、特に好ましくは150~250°Cである。

【0065】耐熱性フィルムとしては、たとえばフッ素樹脂チューブが用いられ、その軸方向長さは、第1接合部分5aよりも長いことが好ましく、たとえば約20mm程度である。チューブの軸方向一端には、長さ約3mm程度の切り込みを形成しても良い。熱融着後に、耐熱性フィルムを除去しやすくするためである。

【0066】その後、第1外チューブ部材6aの軸方向所定位置のチューブ壁に、図4に示すように、内チューブ12が通り抜けられる程度の貫通孔21を形成する。

【0067】次に、造影リング15が装着してある内チューブ12を準備する。内チューブ12に造影リング15を装着するために、本実施形態では、まず図7に示すように、内チューブ12の遠位端から所定距離L_t離れた位置を、滑り止めシート50を介して指などで掴み、内チューブ12の遠位端を矢印方向にプライヤーなどで引っ張る。その結果、所定距離L_tの範囲の内チューブ12の外径は、多少小さくなる。なお、滑り止めシート50としては、ゴムシートが用いられる。また、所定距離L_tとしては、たとえば3~10mmである。

【0068】次に、プライヤーなどで挟んだ部分をかみそりなどで削除し、内チューブ12の遠位端部に形状復元用マンドレルを挿入し、扁平に変形した内チューブの部分を断面円形に戻す。その後、形状復元用マンドレルを引き抜き、代わりに、図8に示す引き抜き加工用マンドレル54を内チューブ12の遠位端部内に挿入する。その状態で、引き抜き加工用ダイ52の円形孔に、内チューブ12の遠位端部を通し、プライヤー56などで、内チューブ12の遠位端部を引き抜き加工する。ダイ5

2は、たとえば40～80℃に加熱してある。

【0069】その結果、内チューブ12の外径は、元の外径D1から縮径され、外径D2の縮径部58が形成される。なお、内チューブ12における縮径部58の内径は、マンドレル54のために元の内チューブ12の内径を維持する。また、図8に示す縮径部58の外径D2は、元の外径D1に対して、 $D2/D1=0.8\sim0.95$ であることが好ましい。また、図9に示す内チューブ12の元の肉厚T1に対して、縮径部58の肉厚T2は、 $T2/T1$ が0.6～0.9の関係となることが好ましい。

【0070】また、縮径部58の外径D2は、造影リング15の内径と同等以下であることが好ましい。図9に示すように、マンドレル54が装着されている縮径部58の外周に造影リング15を容易に装着させるためである。本実施形態では、近位端側に配置される一方の造影リング15を、内チューブ12の元の外径から縮径部58に移る段差部の位置に取り付け、その造影リング15から図4に示す所定距離Lsの位置に、他方の造影リング15を取り付ける。

【0071】その状態で、内チューブ12における縮径部58を、所定温度で加熱する。その所定温度は、内チューブ12を構成する合成樹脂の融点から5～20℃程度、好ましくは、7～15℃程度低温側の範囲にあることが好ましい。たとえば内チューブ12がポリエチレンで構成される場合には、加熱温度は、 $120\pm5^\circ\text{C}$ であることが好ましい。

【0072】内チューブ12における縮径部58を加熱した結果、図6に示すように、縮径部58の外径が復元し、造影リング15を内チューブ12の所定位置に固定することができる。復元後の内チューブ12の外径D4は、元の内チューブ12の外径D1と略同一となる。たとえば $D4/D1$ は、0.9～1の範囲となるように、縮径部58は復元することができる。

【0073】造影リング15の外径D5に対する復元後の内チューブの外径D4の比 $D4/D5$ は、好ましくは0.7～1である。また、造影リング15の内径D3に対する復元後の内チューブ12の外径D4の比 $D4/D3$ は、好ましくは1～1.2である。

【0074】このようにして内チューブ12の遠位端部の所定位置に一方の造影リング15が装着された内チューブ12を製造した後、次のようにして、内チューブ12を、図4に示すバルーン部4の内部に装着する。

【0075】まず、その内チューブ12のルーメン内にワイヤ状マンドレルを通して一体化する。マンドレルが一体化された内チューブ12を貫通孔21から第1外チューブ部材6aの内部ルーメン内を通し、内チューブ12の遠位端をバルーン部4の遠位端封止部分7から突出させ、各造影リング15をバルーン部4の交差部4abおよび4acに位置させる。その前後に、ヒートシール

用チューブを第1外チューブ部材6aの外周に位置させる。

【0076】その後、第1外チューブ部材6aの近位端部からヒートシール用マンドレルを内部に挿入し、マンドレルの先端部を貫通孔21の付近に位置させ、貫通孔21の付近での第1外チューブ6aの潰れを防止する。マンドレルの基端部は、第1外チューブ部材6aの内径と略同一またはそれ以下の外径を有し、その先端部には、内チューブ12の外周を受けるように、軸方向凹部が形成してある。次に、ヒートシール用チューブを第1外チューブ部材6aの外周で軸方向に移動させ、ヒートシール用チューブが、貫通孔21の付近の第1外チューブ6aの外周と、貫通孔21から飛び出す内チューブ12の外側とを、一体的に覆うようにする。その後、ヒートシール用金型を用いて、ヒートシール用チューブの外側から押圧加熱し、貫通孔21の孔縁と内チューブ12の外側管壁とを熱融着する。加熱温度は、特に限定されないが、好ましくは $100\sim300^\circ\text{C}$ 、特に好ましくは $150\sim250^\circ\text{C}$ である。

【0077】その後、マンドレルを取り出すと共に、ヒートシール用チューブを除去する。その後、熱融着工程で熱融着された内チューブ12の外側管壁と貫通孔21の内縁との熱融着部を残し、当該熱融着部から外側に位置する内チューブ12の不要部分をカッタなどで切断して除去する。その結果、内チューブ12の近位端開口部22が、第1外チューブ部材6aのチューブ壁の外側に開口して形成される。近位端開口部22は、この例では、略楕円形状となる。

【0078】なお、これらの工程の前後、または同時に、内チューブ12の遠位端部は、バルーン部4の遠位端封止部分7に対して、同様なヒートシール方法により熱融着され、先端テーパ部7aが形成されるように加工される。詳細を以下に示す。

【0079】まず、図10に示すように、内チューブ12の遠位端部をバルーン部4の遠位端封止部分7の内部に通し、内チューブ12の内部に、その遠位端からマンドレル40を挿入する。その後、内チューブ12の第2接合部分12aに対応する位置で、バルーン部4の遠位端封止部分7の外周を耐熱性フィルム41で覆い、その耐熱性フィルム41を、金型43で加熱する。その結果、バルーン部4の遠位端封止部分7は、耐熱性フィルム41の軸方向長さに対応する融着部44において、内チューブ12の外周に熱融着する。なお、熱融着時には、バルーン4は、内チューブ12の回りに巻回されて折り畳まれ、その外周は、保護チューブなどで保護される。保護チューブとしては、耐熱性のフッ素樹脂チューブが用いられる。

【0080】熱融着時の加熱温度は、特に限定されないが、バルーン部4の近位端封止部分5における熱融着と同様に、好ましくは $100\sim300^\circ\text{C}$ 、特に好ましく

は150～250℃である。また、耐熱性フィルム41としては、たとえばフッ素樹脂チューブが用いられ、チューブの軸方向一端には、長さ約3mm程度の切り込みを形成しても良い。熱融着後に、耐熱性フィルム41を除去しやすくするためである。

【0081】融着部44において、遠位端封止部分7が内チューブ12の外周に熱融着後に、金型43を取り外し、耐熱性フィルム41を除去し、マンドレル40を取り除いた後、遠位端封止部分7における先端側の不要部分7bを除去する。不要部分7bの除去に際しては、遠位端封止部分7における融着部44の遠位端側には、未融着部分46が形成されるため、カッタなどで簡単に除去することができる。その後、滑らかな先端テーパ面7aが形成されるように、遠位端封止部分7の先端テーパ面7aを、たとえば研磨用回転ディスクの回転面に押し付けて研磨加工する。その後、図5に示すように、内チューブ12の遠位端部を、所定長さLfに切断し、その切断面を面取り加工して、テーパ面12cを形成する。

【0082】その後、第1外チューブ部材6aの近位端部に第2外チューブ部材6bの遠位端部を接合する。その接合に際して、まず、第2外チューブ部材6bの外周に、ヒートシール用チューブを被せ、第1外チューブ6aの近位端部のルーメン内に、第2外チューブ部材6bの遠位端部を押し込む。その後、第2外チューブ部材6bの第3ルーメン24の内部に、軸方向に沿ってマンドレルを挿入し、その先端を第1外チューブ部材6aの内部まで突出させる。その前後または同時に、第2外チューブ部材6bの第4ルーメン26の内部に軸方向に沿って補強ロッド28を挿入し、その先端部を第1外チューブ部材6aの外周に形成してある近位端開口部22の下まで位置させる。

【0083】その後、ヒートシール用チューブを軸方向に移動させ、このヒートシール用チューブで、第1外チューブ部材6aと第2外チューブ部材6bとの接合部9を覆い、金型を用いて、前述したヒートシール条件と同様なヒートシール条件で熱融着を行う。

【0084】その後、ヒートシール用チューブを取り除くと共に、マンドレルを取り除き、第2外チューブ部材6bの近位端部に、図1に示すコネクタ8を熱融着などの手段で接合する。その後、必要に応じて、外チューブ6の外周面に、湿潤状態で潤滑性を持つ親水性高分子物質から成る被覆材を被覆し、図1に示すバルーンカテーテル2を得る。

【0085】次に、図1に示す実施形態のバルーンカテーテル2を用いて、PTCA治療を行う方法について説明する。まず、バルーンカテーテル2内の空気をできる限り除去する。そこで、コネクタ8のポートには、シリンジなどの吸引・注入手段を取り付け、シリンジ内に血液造影剤（たとえばヨウ素含有）などの液体を入れ、吸引および注入を繰り返し、第3ルーメン24、第1ルー

メン10およびバルーン部4内の空気を液体と置換する。

【0086】バルーンカテーテル2を動脈血管内に挿入するには、まず、セルジnger法などにより、血管内にガイドカテーテル用ガイドワイヤ（図示せず）を、その先端がたとえば心臓の近くまで届くように挿入する。その後、ガイドカテーテル用ガイドワイヤに沿って、ガイドカテーテルを、動脈血管内に挿入し、その先端を狭窄部を有する心臓の冠動脈入口に位置させる。なお、狭窄部は、たとえば血栓または動脈硬化などにより形成される。

【0087】次に、ガイドカテーテル用ガイドワイヤのみを抜き取り、それよりも細いバルーンカテーテル用ガイドワイヤをガイドカテーテルに沿って挿入し、その先端を狭窄部を通過する位置まで差し込む。

【0088】その後、ガイドワイヤの遠位端を、図1に示すバルーンカテーテル2の遠位開口端20に差し込み、第1ルーメン14内に通し、近位端開口部22から引き出す。そして、バルーン部4が折り畳まれた状態で、バルーンカテーテル2を、ガイドワイヤ42に沿って、ガイドカテーテル内に通す。そして、図11に示すように、バルーンカテーテル2のバルーン部4を、血管34中の狭窄部36の手前まで差し込む。

【0089】その後、バルーンカテーテル2の折り畳まれたバルーン部4をガイドワイヤに沿って、狭窄部間に差し込む。次に、バルーン部4の位置をX線透視装置などで観察しながら、狭窄部の中央部にバルーン部4を正確に位置させる。その位置でバルーン部4を膨らますことにより、血管の狭窄部を広げ、良好な治療を行うことができる。なお、バルーン部4を膨らますには、図1に示すコネクタ8のポートから第3ルーメン24および第1ルーメン10を通して、バルーン部4内に液体を注入することにより行う。

【0090】この膨張時間は、特に限定されないが、たとえば約1分間程度である。その後、迅速にバルーン部4から液体を抜いてバルーン部を収縮させ、拡張された狭窄部の末梢側の血流を確保する。狭窄部の拡張は、血管を傷つけないように、段階的に行う必要があり、最初は小さい外径のバルーン部4を持つバルーンカテーテル2をガイドワイヤに沿って挿入し、順次大きな外径のバルーン部4を持つバルーンカテーテル2と交換する。その際に、本実施形態に係るバルーンカテーテル2は、モノレール方式のバルーンカテーテルであることから、内チューブ12の長さに相当する部分より僅かに長い程度にガイドワイヤ42の近位端部を体外側に延ばしておくだけで、バルーンカテーテルの交換作業を行うことができる。

【0091】本実施形態に係るバルーンカテーテル2では、バルーンカテーテル2の遠位端部のみを、外チューブ6と内チューブ12とから成る、いわゆる同軸構造の

カテーテルチューブ構造を採用し、内チューブ12のルーメン14をガイドワイヤ挿通用ルーメンとして用いている。このため、いわゆるダブルルーメンのカテーテルチューブを有する従来のバルーンカテーテル（特開昭63-288167号公報や特開平2-307479号公報）に比較し、本実施形態に係るバルーンカテーテル2では、第1外チューブ部材6aの外径を細くし易い。また、本実施形態に係るバルーンカテーテル2では、ガイドワイヤの近位端側取り出し口となる内チューブ12の近位端開口部22が、外チューブ6の長手方向の途中に位置するチューブ壁を貫通して外部に開口しており、その開口部22では、内チューブ12と外チューブ6との二重構造となり、キンクし難い構造となっている。

【0092】さらに本実施形態に係るバルーンカテーテル2では、ガイドワイヤ42の近位端側取り出し口となる内チューブ12の近位端開口部22が、外チューブ6の長手方向の途中に位置するチューブ壁を貫通して外部に開口しているのみであり、カテーテルチューブ2の全長に亘り、段差を作る必要がなく、バルーンカテーテル2の挿入特性に優れている。また、キンクし難い構造であることから、バルーンカテーテル2の押し込み特性にも優れている。

【0093】また、本実施形態では、図2に示すように、補強ロッド28を、開口部22付近から近位端側の第1外チューブ部材6aの内部に配置してあるため、バルーンカテーテルの押し込み特性がさらに向上すると共に、カテーテルチューブの遠位端側が柔軟になり、曲がりくねった血管などの体腔内での挿入特性がさらに向上する。

【0094】さらに本実施形態では、補強ロッド28の遠位端部28aが第1外チューブ部材6aの内壁に対して固定されていないので、バルーンカテーテル2を、冠動脈のように分岐部分が多く且つ細い血管に挿入する場合でも、第1外チューブ部材6aの遠位端部が、血管の屈曲部分に対応して柔軟に変形する。これは、補強ロッド28の遠位端部28aが第1外チューブ部材6aの内壁に固定されていないことから、第1外チューブ部材6aの遠位端部が、補強ロッド28に制限されることなく、自由に変形できるためと考えられる。

【0095】さらにまた本実施形態では、バルーン部4の近位端封止部分5が、外チューブ6の遠位端部に重複して接合される第1接合部分5aと、重複していない第1非接合部分5bとを有する。バルーン部4の近位端封止部分5における第1非接合部分5bは、バルーン部4の拡張による治療効果にほとんど寄与しない部分であるが、その部分を設けることにより、バルーンカテーテル2の遠位端部における柔軟性が向上する。第1非接合部分5bは、バルーン部4の一部であり、外チューブ部6よりも柔軟性があるからである。

【0096】したがって、本実施形態のバルーンカテー

テル2を、冠動脈のように分岐部分が多く且つ細い血管に挿入する場合でも、バルーンカテーテル2の遠位端部が、血管の屈曲部分に対応して柔軟に変形する。すなわち、本実施形態のバルーンカテーテル2においては、バルーンカテーテル2の挿入特性および押し込み特性が向上する。

【0097】また本実施形態では、内チューブ12の遠位端部に接合されるバルーン部4の遠位端封止部分7には、内チューブ12の遠位端外周に向けて外径が細くなる先端テーパ部7aが形成してある。しかも、内チューブ12の遠位端部外周には、バルーン部4の遠位端封止部分7が接合されていない第2非接合部分12bが形成してある。

【0098】このため、図11に示すように、バルーンカテーテル2の遠位端の外径が、内チューブ12の外径に等しくなり、特に狭窄の程度が激しい場合や、曲がりくねった血管34の狭窄部36に対しても、バルーンカテーテル2の遠位端を、容易に挿入することが可能である。したがって、バルーンカテーテル2の挿入特性が向上する。

【0099】特に、本実施形態では、造影リング15が装着される位置を含む所定長さ範囲の内チューブ12の外径を強制的に縮径させ、造影リング15の内径と同等以下の外径を持つ縮径部58を形成するので、内チューブ12の縮径部58に造影リング15を装着する作業が容易である。その縮径部58に造影リング15を装着し、その後、加熱することにより、縮径部58の外径は、元の外径近くまで復元する。したがって、造影リング15は、図6に示すように、内チューブ12の外周に埋め込まれる構造となり、その所定位置に固定される。

【0100】このようにして製造されたバルーンカテーテル2は、造影リング15が内チューブ12の外周に埋め込まれる構造となり、その造影リング15の装着位置において、造影リング15が内チューブ12の外周から過度に突出することが無くなる。その結果、バルーン部4を内チューブ12の外周に折り畳んだ状態で、その外径を小さくすることが可能になり、特に狭窄の程度が激しい場合や、曲がりくねった血管の狭窄部に対しても、バルーンカテーテル2の遠位端を、容易に挿入することが可能である。したがって、バルーンカテーテル2の挿入特性が向上する。

【0101】また、本実施形態に係るバルーンカテーテルの製造方法では、バルーンカテーテルを、比較的2容易に製造することができ、造影リング15と内チューブ12との接合強度も十分であり、しかも、その製造に際し、内チューブが極度に薄肉になるなどの欠陥などが生じにくい。また、造影リング15と内チューブ12との接合に際し、必ずしも接着剤などを必要としない。

【0102】なお、本発明は、上述した実施形態に限定されるものではなく、本発明の範囲内で種々に改変する

ことができる。たとえば上述した実施形態では、外チューブ6を第1外チューブ部材6aと第2外チューブ部材6bとで構成したが、本発明では、外チューブ6を軸方向に連続する単一のチューブで構成することも可能である。また、本発明に係るバルーンカテーテルの用途は、上述した用途に限定されるものではない。

【0103】さらに、本発明は、バルーンカテーテルに限らず、チューブの外周に電極やセンサなどとして用いられる金属リング（上記実施形態において造影リング15に対応する）が取り付けられる医療器具にも適用することが可能である。チューブの外周に電極が取り付けられる医療器具としては、たとえば電極カテーテルなどが例示される。

【0104】

【発明の効果】以上説明してきたように、本発明によれば、金属リングが取り付けられるチューブ部分の外径を極力小さくでき、体腔内への挿入性に優れた医療器具と、その医療器具を、チューブに欠陥を生じさせることなく、きわめて容易に製造することができる医療器具の製造方法を提供することができる。

【0105】また、本発明によれば、特に狭窄の程度が激しい場合や、曲がりくねった血管の狭窄部に対して、バルーンカテーテルの遠位端を、容易に挿入することが可能であり、挿入特性に優れたバルーンカテーテルと、そのバルーンカテーテルを、内チューブに欠陥を生じさせることなく、きわめて容易に製造することができるバルーンカテーテルの製造方法とを提供することができる。

【図面の簡単な説明】

【図1】 図1は本発明の1実施形態に係るバルーンカテーテルの全体構成図である。

【図2】 図2（A）図1に示すIIB-IIB線に沿う断面図、図2（B）は図1に示すIIB-IIB線に沿う断面図、図2（C）は図1に示すIIC-IIC線に沿う断面図、図2（D）は図1に示すIID-IID線に沿う断面図である。

【図3】 図3は図1に示す補強ロッドの側面図である。

【図4】 図4は図1に示すバルーンカテーテルの要部縦断面図である。

【図5】 図5は図4に示すバルーンカテーテルの遠位端部の詳細を示す要部断面図である。

【図6】 図6はバルーン部内に位置する内チューブに

対する造影リングの取り付け構造を示す要部断面図である。

【図7】 図7は内チューブに対する造影リングの取り付け方法を示す要部側面図である。

【図8】 図8は図7の続きの構成を示す要部断面図である。

【図9】 図9は図8の続きの工程を示す要部断面図である。

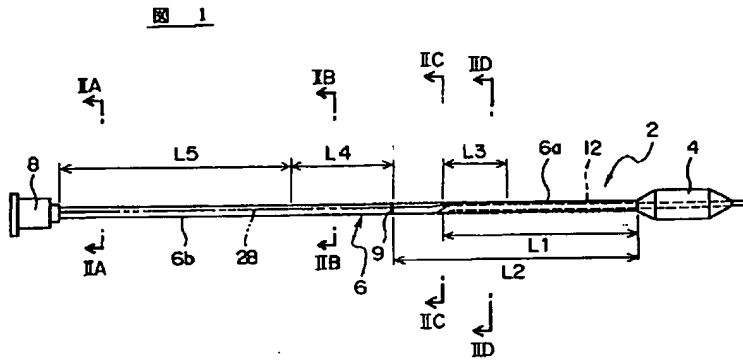
【図10】 図10はバルーン部の遠位端封止部分と内チューブの遠位端部との接合工程を示す要部断面図である。

【図11】 図11は図1に示すバルーンカテーテルの使用例を示す要部断面図である。

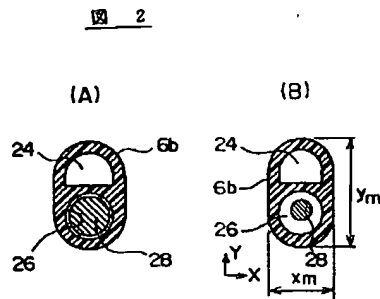
【符号の説明】

- 2… バルーンカテーテル
- 4… バルーン部
- 4a… 筒状部分
- 4b, 4c… テーパー状縮径部分
- 5… 近位端封止部分
- 5a… 第1接合部分
- 5b… 第1非接合部分
- 7… 遠位端封止部分
- 7a… 先端テーパー部
- 7b… 不要部分
- 6… 外チューブ
- 6a… 第1外チューブ部材
- 6b… 第2外チューブ部材
- 8… コネクタ
- 10… 第1ルーメン
- 12… 内チューブ
- 12a… 第2接合部分
- 12b… 第2非接合部分
- 14… 第2ルーメン
- 15… 造影リング
- 20… 遠位端開口部
- 21… 貫通孔
- 22… 近位端開口部
- 24… 第3ルーメン
- 26… 第4ルーメン
- 28… 補強ロッド
- 44… 融着部
- 58… 縮径部

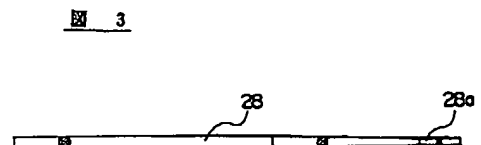
【図1】



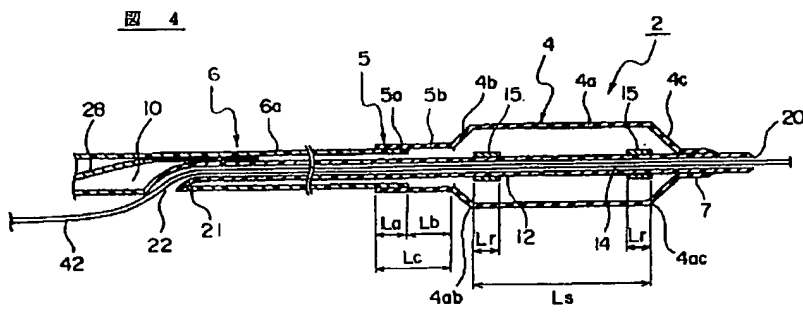
【図2】



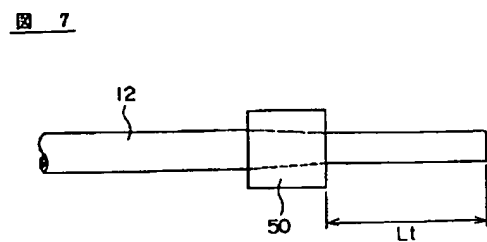
【図3】



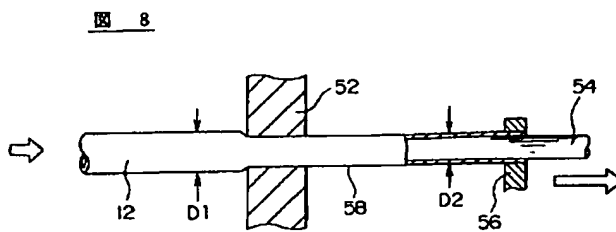
【図4】



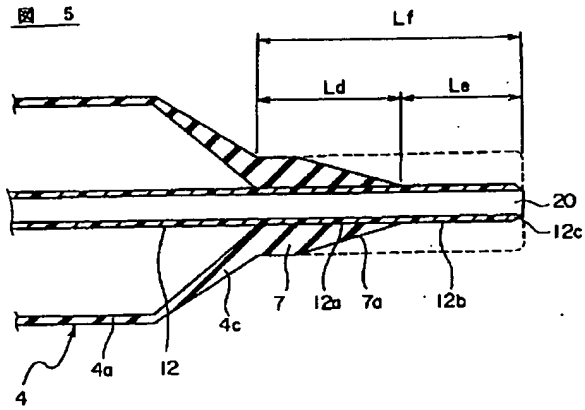
【図7】



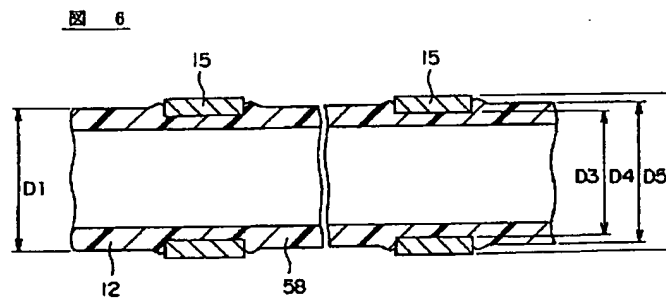
【図8】



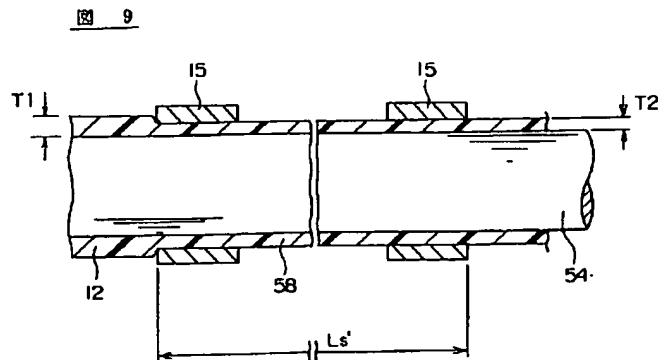
【図5】



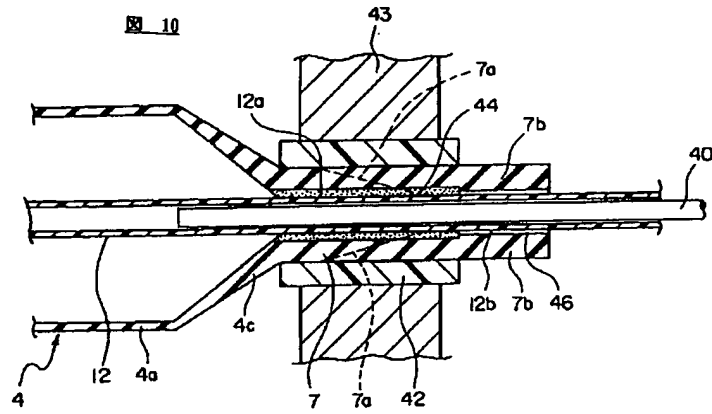
【図6】



【図9】



【図10】



【図11】

